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PA 1272595

# THE UNITED STATES OF AMERICA

**TO ALL TO WHOM THESE PRESENTS SHALL COME:**

**UNITED STATES DEPARTMENT OF COMMERCE**

**United States Patent and Trademark Office**

**January 18, 2005**

**THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM  
THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK  
OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT  
APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A  
FILING DATE UNDER 35 USC 111.**

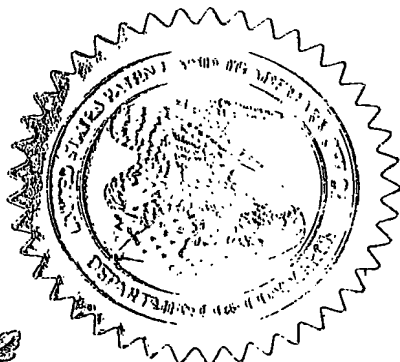
**APPLICATION NUMBER: 10/967,922**

**FILING DATE: October 18, 2004**

**By Authority of the  
COMMISSIONER OF PATENTS AND TRADEMARKS**

*L. Edelen*

**L. EDELEN  
Certifying Officer**



**BEST AVAILABLE COPY**

101804

22783

Practitioner's Docket No. U 015413-4

PATENT

## Preliminary Classification:

Proposed Class:

Subclass:

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.'" M.P.E.P. Section 601, 7th ed.

19270 U.S. PTO  
10/967922

101804

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mail Stop Patent Application  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Optional Customer No. Bar Code



00140

PATENT TRADEMARK OFFICE

## NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of  
Inventor(s):

OZ CABIRI  
YOSSI GROSS

**WARNING:** 37 C.F.R. Section 1.41(a)(1) points out:

"(a) A patent is applied for in the name or names of the actual inventor or inventors.

(1) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by Section 1.63, except as provided for in Section 1.53(d)(4) and Section 1.63(d). If an oath or declaration as prescribed by Section 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to Section 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in Section 1.17(f) is filed supplying or changing the name or names of the inventor or inventors."

For (title): **PRESSURE-PROPELLED SYSTEM FOR BODY LUMEN**

## CERTIFICATION UNDER 37 C.F.R. 1.10\*

(Express Mail label number is mandatory.)

(Express Mail certification is optional.)

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the United States Postal Service on this date October 18, 2004, in an envelope as "Express Mail Post Office to Addressee", mailing Label Number EV 481671000 US, addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450

GERALDINE MARTI

(type or print name of person mailing paper)

Signature of person mailing paper

**WARNING:** Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).  
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

EXPRESS MAIL LABEL

(New Application Transmittal--page 1 of 15) 4-1

## 1. Type of Application

This new application is for a(n)

*(check one applicable item below)*

- ☐ Original (nonprovisional)
- ☐ Design
- ☐ Plant

**WARNING:** *Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4), unless the International Application is being filed as a divisional, continuation or continuation-in-part application.*

**WARNING:** *Do not use this transmittal for the filing of a provisional application.*

**NOTE:** If one of the following 3 items apply, then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

- ☐ Divisional.
- ☐ Continuation.
- ☒ Continuation-in-part (C-I-P).

## 2. Benefit of Prior U.S. Application(s) (35 U.S.C. Sections 119(e), 120, or 121)

**NOTE:** *A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. Section 112. Each prior application must also be:*

*(i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or*

*(ii) Complete as set forth in Section 1.51(b); or*

*(iii) Entitled to a filing date as set forth in Section 1.53(b) or Section 1.53(d) and include the basic filing fee set forth in Section 1.16; or*

*(iv) Entitled to a filing date as set forth in Section 1.53(b) and have paid therein the processing and retention fee set forth in Section 1.21(l) within the time period set forth in Section 1.53(f).*

37 C.F.R. Section 1.78(a)(1).

**WARNING:** *If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. §§120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. §§ 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. §§ 119, 365(a) or 365(b).) For a C-I-P application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.*

**WARNING:** 37 C.F.R. § 1.78(a)(2) deals with the time in which the claim for the benefit of an earlier filing date must be made and states:

"(2)(i) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross references to other related applications may be made when appropriate (see § 1.14).

(ii) This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. If the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) (in the later-filed international application sixteen months from the filing date of the prior-filed application. These time periods are not extendable. Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (a)(2)(i) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior-filed application. The time periods in this paragraph do not apply if the later-filed application is:

- (A) An application for a design patent;
- (B) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or
- (C) A nonprovisional application which entered the national stage after compliance with 35 U.S.C. 371 from an international application filed under 35 U.S.C. 363 before November 29, 2000.

(iii) If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence following the title.

(iv) The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior-filed application. The identification of an application by application number under this section is the identification of every application assigned that application number necessary for a specific reference required by 35 U.S.C. 120 to every such application assigned that application number."

**NOTE:** If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

☒ [X] The new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

### 3. Papers Enclosed

#### A. Required for Filing Date under 37 C.F.R. Section 1.53(b) (Regular) or 37 C.F.R. Section 1.153 (Design) Application

58 Pages of Specification including claim  
35 Pages of Claims  
9 Sheets of Drawing

**WARNING:** *DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to Section 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. For comments on proposed then-new 37 C.F.R. 1.84, see Notice of March 9, 1988 . (1990 O.G. 57-62).*

**NOTE:** *"Identification of drawings. Identifying indicia, if provided, should include the title of the invention, inventor's name and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin."*

*(complete the following, if applicable)*

☐ The enclosed drawing(s) are photograph(s).

**NOTE:** 37 C.F.R. 1.84  
"(b) Photographs.

*"(1) Black and white. Photographs, including photocopies of photographs, are not ordinarily permitted in utility and design patent applications. The Office will accept photographs in utility and design patent applications, however, if photographs are the only practicable medium for illustrating the claimed invention. For example, photographs, or photomicrographs of: electrophoresis gels, blots (e.g., immunological, western, Southern and northern), auto radiographs, cell cultures (stained and unstained), histological tissue cross sections (stained and unstained), animals, plants, in vivo imaging, thin layer chromatography plates, crystalline structures, and in a design patent application, ornamental effects, are acceptable. If the subject matter of the application admits of illustration by a drawing, the examiner may require a drawing in place of the photograph. The photographs must be of sufficient quality so that all details in the photographs are reproducible in the printed patent.*

*"(2) Color photographs. Color photographs will be accepted in utility and design patent applications if the conditions for accepting color drawings and black and white photographs have been satisfied. See paragraphs (a)(2) and (b)(1) of this section."*

☐ The enclosed drawing(s) are in color. Three (3) sets of color drawings and a "PETITION TO ACCEPT COLOR DRAWING(S)" are attached. 37 C.F.R. §§ 1.84(a)(2) and 1.84(b).

**NOTE:** 37 C.F.R. 1.84(a)

*"(2) Color. On rare occasions color drawings may be necessary as the only practical medium by which to disclose the subject matter sought to be patented in a utility or design patent application or the subject matter of a statutory invention registration. The color drawings must be of sufficient quality such that all details in the drawings are reproducible in black and white in the printed patent. Color drawings are not permitted in international applications (see PCT Rule 11.13), or in an application, or copy thereof, submitted under the Office electronic filing system. The Office will accept color drawings in utility or design patent applications and statutory invention registrations only after granting a petition filed under this paragraph explaining why the color drawings are necessary. Any such petition must include the following:*

- (i) The fee set forth in § 1.17(h);*
- (ii) Three (3) sets of color drawings;*
- (iii) A black and white photocopy that accurately depicts, to the extent possible, the subject matter shown in the color drawing; and*

- (iv) *An amendment to the specification to insert (unless the specification contains or has been previously amended to contain) the following language as the first paragraph of the brief description of the drawings:*

*"The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee."*

- ☒ Formal  
☐ Informal

**B. Other Papers Enclosed**

- \_\_\_\_ Pages of declaration and power of attorney  
  1   Pages of Abstract  
\_\_\_\_ Other

**4. Additional Papers Enclosed**

- ☐ Preliminary Amendment  
☐ Information Disclosure Statement (37 C.F.R. Section 1.98)

**WARNING:** *In order to ensure consideration of information previously submitted but which has not been considered in the parent application, an applicant must resubmit the information, complying with 37 C.F.R. § 1.97 and 37 C.F.R. § 1.98, in the continuing application filed under 37 C.F.R. § 1.53(b). See § 609B(3), M.P.E.P., 7<sup>th</sup> Edition, Rev. 1.*

- ☐ Form PTO-1449 (PTO/SB/08A and 08B)  
☐ Citations  
☐ Statement of Biological Deposit  
☐ Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.  
☐ Authorization of Attorney(s) to Accept and Follow Instructions from Representative  
☐ Special Comments  
☐ Request for Nonpublication of Application  
☐ Other

**5. Declaration or Oath (including power of attorney)**

**NOTE:** *A newly executed declaration is not required in a continuation or divisional application provided the prior nonprovisional application contained a declaration as required, the application being filed is by all or fewer than all the inventors named in the prior application, there is no new matter in the application being filed, and a copy of the executed declaration filed in the prior application (showing the signature or an indication thereon that it was signed) is submitted. The copy must be accompanied by a statement requesting deletion of the names of person(s) who are not inventors of the application being filed. If the declaration in the prior application was filed under Section 1.47 then a copy of that declaration must be filed accompanied by a copy of the decision granting Section 1.47 status or, if a nonsigning person under Section 1.47 has subsequently joined in a prior application, then a copy of the subsequently executed declaration must be filed. See 37 C.F.R. Section 1.63(d)(1)-(3).*

**NOTE:** *A declaration filed to complete an application must be executed, identify the specification to which it is directed, identify each inventor by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and the residence, post office address and country of citizenship of each inventor, and state whether the inventor is a sole or joint inventor. 37 C.F.R. Section 1.63(a)(1)-(4).*

**NOTE:** *The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by Section 1.62, except as provided for in Section 1.53(d)(4) and Section 1.63(d). If an oath or declaration as prescribed by Section 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to Section 1.53(b), unless, a petition under this paragraph accompanied by the fee set forth in Section 1.17(I) is filed supplying or changing the name or names of the inventor or inventors. 37 C.F.R. Section 1.41(a)(1).*

☐ Enclosed

Executed by

*(check all applicable boxes)*

- ☐ inventor(s).
- ☐ legal representative of inventor(s). 37 C.F.R. Section 1.42 or 1.43.
- ☐ joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

- ☐ This is the petition required by 37 C.F.R. Section 1.47 and the statement required by 37 C.F.R. Section 1.47 is also attached. See item 13 below for fee.

☒ Not Enclosed.

**NOTE:** *Where the filing is a completion in the U.S. of an International Application, or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.*

- ☒ Application is made by a person authorized under 37 C.F.R. 1.41 on behalf of all the above named inventor(s).

- ☐ Showing that the filing is authorized.  
*(not required unless called into question. 37 C.F.R. Section 1.41(d))*

6. Inventorship Statement

**WARNING:** *If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.*

The inventorship for all the claims in this application are:

☐ The same.

or

☐ Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,  
☐ is submitted.  
☐ will be submitted.

7. Language

**NOTE:** *An application including a signed oath or declaration may be filed in a language other than English. An English translation of the non-English language application and the processing fee of \$130.00 required by 37 C.F.R. Section 1.17(k) is required to be filed with the application, or within such time as may be set by the Office. 37 C.F.R. Section 1.52(d).*

☒ English  
☐ Non-English

☐ The attached translation includes a statement that the translation is accurate.  
37 C.F.R. Section 1.52(d).

8. Assignment

☒ An assignment of the invention to G.I. VIEW LTD.

☐ is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.

☒ will follow.

☐ has been recorded at Reel\_\_\_\_\_, Frame\_\_\_\_\_ on \_\_\_\_\_

**NOTE:** *"If an assignment is submitted with a new application, send two separate letters-one for the application and one for the assignment" Notice of May 4, 1990 (1114 O.G. 77-78).*

**WARNING:** *A newly executed "STATEMENT UNDER 37 C.F.R. Section 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.*



9. Certified Copy

Certified copy(ies) of application(s)

|         |            |       |
|---------|------------|-------|
| Country | Appln. no. | Filed |
| Country | Appln. no. | Filed |
| Country | Appln. no. | Filed |

from which priority is claimed

- ☐ is (are) attached.  
☐ will follow.  
☐ was filed in parent application \_\_\_\_\_

NOTE: 37 C.F.R. §1.55. Claim for foreign priority.

"(a) \* \* \*

*(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. This time period is not extendable. The claim must identify the foreign application for which priority is claimed, as well as any foreign application for the same subject matter and having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time periods in this paragraph do not apply in an application under 35 U.S.C. 111(a) if the application is:*

- (A) A design application; or*  
*(B) An application filed before November 29, 2000.*

*\* \* \* \**

*(C) Unless such claim is accepted in accordance with the provisions of this paragraph, any claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) not presented within the time period provided by paragraph (a) of this section is considered to have been waived. If a claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) is presented after the time period provided by paragraph (a) of this section, the claim may be accepted if the claim identifying the prior foreign application by specifying its application number, country (or intellectual property authority), and the day, month, and year of its filing was unintentionally delayed. A petition to accept a delayed claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) must be accompanied by:*

*(1) The claim under 35 U.S.C. 119(a)-(d) or 365(a) and this section to the prior foreign application, unless previously submitted;*

*(2) The surcharge set forth in § 1.17(i); and*

*(3) A statement that the entire delay between the date the claim was due under paragraph (a)(1) of this section and the date of the claim was filed was intentional. The Commissioner may require additional information where there is a question whether the delay was intentional."*

NOTE: 37 C.F.R. § 1.63 Oath or declaration.

"(a) An oath or declaration filed under § 1.51(b)(2) as a part of a nonprovisional application must:

\*\*\*\*\*

(c) Unless such information is supplied on an application data sheet in accordance with § 1.76, the oath or declaration must also identify:

(2) An foreign application for patent (or inventor's certificate) for which a claim for priority is made pursuant to § 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing."

The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 C.F.R. § 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. IF any parent U.S. application or international Application form which this application claims benefit under 35 U.S.C. § 120 is itself entitled to priority from a prior foreign application, then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

#### 10. Fee Calculation (37 C.F.R. Section 1.16)

A. ☒ Regular application

| CLAIMS AS FILED  |              |                     |              |          |  |
|--|--------------|---------------------|--------------|----------|--|
| Claims   | Number Filed | Basic Fee Allowance | Number Extra | Rate     | Basic Fee 37 C.F.R. Section 1.16(a) \$790.00 |
| Total Claims<br>(37 C.F.R. Section 1.16(c))                        | 301          | -20 =               | x 281        | \$ 18.00 | 5,058.00                                     |
| Independent Claims<br>(37 C.F.R. Section 1.16(b))                  | 27           | - 3 =               | x 24         | \$ 88.00 | 2,112.00                                     |
| Multiple Dependent Claim(s), if any<br>(37 C.F.R. Section 1.16(d)) |              |                     |              | \$300.00 |  |

- ☐ Amendment canceling extra claims is enclosed or above.
- ☐ Amendment deleting multiple-dependencies is enclosed.
- ☐ Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims canceled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 C.F.R. Section 1.16(d).

Filing Fee Calculation \$ 7,960.00

B. ☐ Design application  
(\$350.00--37 C.F.R. Section 1.16(f))  
Filing Fee Calculation \$ \_\_\_\_\_

C. ☐ Plant application  
(\$550.00--37 C.F.R. Section 1.16(g))  
Filing Fee Calculation \$ \_\_\_\_\_

11. Small Entity Statement(s)

- ☒ Statement(s) or Written Assertion(s) that this is a filing by a small entity under 37 C.F.R. Section 1.9 and 1.27 is (are) attached.
- ☒ Applicant hereby asserts small entity status by paying the small entity filing fee.

**NOTE:** 37 C.F.R. § 1.27(c) deals with the assertion of small entity status; whether by a written specific declaration thereof or by payment as a small entity of the basic filing fee or the fee for the entry into the national phase and states:

*"(c) Assertion of small entity status. Any party (person, small business concern or nonprofit organization) should make a determination, pursuant to paragraph (f) of this section, of entitlement to be accorded small entity status based on the definitions set forth in paragraph (a) of this section, and must, in order to establish small entity status for the purpose of paying small entity fees, actually make an assertion of entitlement to small entity status, in the manner set forth in paragraphs (c)(1) or (c)(3) of this section, in the application patent in which such small entity fees are to be paid.*

(1) *Assertion by writing. Small entity status may be established by a written assertion of entitlement to small entity status. A written assertion must:*

- (i) *Be clearly identifiable;*
- (ii) *Be signed (see paragraph (c)(20) of this section); and*
- (iii) *Convey the concept of entitlement to small entity status, such as by stating that applicant is a small entity, or that small entity status is entitled to be asserted for the application or patent. While no specific words or wording are required to assert small entity status, the intent to assert small entity status must be clearly indicated in order to comply with the assertion requirement.*

(2) *Parties who can sign and file the written assertion. The written assertion can be signed by:*

- (i) *One of the parties identified in § 1.33(b) (e.g., an attorney or agent registered with the Office), § 3.73(b) of this chapter notwithstanding, who can also file the written assertion;*
- (ii) *At least one of the individuals identified as an inventor (even though a § 1.63 executed oath or declaration has not been submitted), notwithstanding § 1.33(b)(4), who can also file the written assertion pursuant to the exception under § 1.33(b) of this part; or*
- (iii) *An assignee of an undivided part interest, notwithstanding §§ 1.33(b)(3) and 3.73(b) of this chapter, but the partial assignee cannot file the assertion without resort to a party identified under § 1.33(b) of this part.*

(3) *Assertion by payment of the small entity basic filing or basic national fee. The payment, by any party, of the exact amount of one of the small entity basic filing fees set forth in §§ 1.16(a), (f), (g), (h), or (k), or one of the small entity basic national fees set forth in §§ 1.492(a)(1), (a)(2), (a)(3), (a)(4), or (a)(5), will be treated as a written assertion of entitlement to small entity status even if the type of basic filing or basic national fee is inadvertently selected in error.*

(i) *If the Office accords small entity status based on payment of a small entity basic filing or basic national fee under paragraph (c)(3) of this section that is not applicable to that application, any balance of the small entity fee that is applicable to that application will be due along with the appropriate surcharge set forth in § 1.16(e), or § 1.16(l).*

(ii) *The payment of any small entity fee other than those set forth in paragraph (c)(3) of this section (whether in the exact fee amount or not) will not be treated as a written assertion of entitlement to small entity status and will not be sufficient to establish small entity status in an application or a patent."*

**WARNING:** 37 C.F.R. § 1.27(c)(4): "Assertion required in related, continuing, and reissue applications. Status as a small entity must be specifically established by an assertion in each related, continuing and reissue application in which status is appropriate and desired. Status as a small entity in one application or patent does not affect the status of any other application or patent, regardless of the relationship of the applications or patents. The refiling of an application under § 1.53 as a continuation, divisional, or continuation-in-part application (including a continued prosecution application under § 1.53(d)), or the filing of a reissue application, requires a new assertion as to continued entitlement to small entity status for the continuing or reissue application."

**WARNING:** "Small entity status must not be established when the person or persons signing the . . . statement can unequivocally make the required self-certification." M.P.E.P. Section 509.03, 6th ed., rev. 2, July 1996 (emphasis added).

(complete the following, if applicable)

☐ Status as a small entity was claimed in prior application  
\_\_\_\_\_, filed on \_\_\_\_\_ from which benefit is being claimed  
for this application under:

|                   |                          |                       |
|-------------------|--------------------------|-----------------------|
| 35 U.S.C. Section | <input type="checkbox"/> | 119(e) - provisional, |
|                   | <input type="checkbox"/> | 120 - continuation,   |
|                   | <input type="checkbox"/> | 121- divisional,      |
|                   | <input type="checkbox"/> | 365(c) - PCT,         |

and which status as a small entity is still proper and desired.

☐ A copy of the statement or written assertion in the prior application is included.

Filing Fee Calculation (50% of A, B or C above) \$ 2,480.00

**NOTE:** A refund based on establishment of small entity status, of a portion of fees timely paid in full prior to establishing status as a small entity may only be obtained if an assertion under § 1.27(c) and a request for a refund of the excess amount are filed within three months of the date of the timely payment of the full fee. The three-month time period is not extendable under § 1.136. 37 C.F.R. § 1.28(a).

12. Request for International-Type Search (37 C.F.R. Section 1.104(d))

*(complete, if applicable)*

- ☐ Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made at This Time

- ☒ Not Enclosed

- ☒ No filing fee is to be paid at this time and any and all prior fee authorizations are revoked.  
*(This and the surcharge required by 37 C.F.R. Section 1.16(e) can be paid subsequently.)*

- ☐ Enclosed

- ☐ Filing fee \$ \_\_\_\_\_
- ☐ Recording assignment  
(\$40.00; 37 C.F.R. Section 1.21(h))  
(See attached "COVER SHEET FOR  
ASSIGNMENT ACCOMPANYING NEW  
APPLICATION.") \$ \_\_\_\_\_
- ☐ Petition and fee for filing by other  
than all the inventors or person  
on behalf of the inventor where  
inventor refused to sign or cannot  
be reached  
(\$130.00; 37 C.F.R. Sections 1.47 and 1.17(l)) \$ \_\_\_\_\_
- ☐ For processing an application with a  
specification in a non-English language  
(\$130.00; 37 C.F.R. Sections 1.52(d) and 1.17(k)) \$ \_\_\_\_\_
- ☐ Processing and retention fee  
(\$130.00; 37 C.F.R. Sections 1.53(d) and 1.21(l)) \$ \_\_\_\_\_
- ☐ Fee for international-type search report  
(\$40.00; 37 C.F.R. Section 1.21(e)) \$ \_\_\_\_\_

NOTE: 37 C.F.R. Section 1.21(l) establishes a fee for processing and retaining any application that is abandoned for failing to complete the application pursuant to 37 C.F.R. Section 1.53(f) and this, as well as the changes to 37 C.F.R. Section 1.53 and 1.78(a)(1), indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid, or the processing and retention fee of Section 1.21(l) must be paid, within 1 year from notification under Section 53(f).

Total Fees Enclosed \$ \_\_\_\_\_

**14. Method of Payment of Fees**

- ☐ Check in the amount of \$\_\_\_\_\_
- ☐ Charge Account No. 12-0425 in the amount of \$\_\_\_\_\_.  
A duplicate of this transmittal is attached.

**15. Authorization to Charge Additional Fees**

**WARNING:** *If no fees are to be paid on filing, the following items should not be completed.*

**WARNING:** *Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.*

- ☐ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No.\_\_\_\_\_.
- ☐ 37 C.F.R. Section 1.16(a), (f) or (g) (filing fees)
- ☐ 37 C.F.R. Section 1.16(b), (c) and (d) (presentation of extra claims)

**NOTE:** *Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims canceled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. Section 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.*

- ☐ 37 C.F.R. Section 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)
- ☐ 37 C.F.R. Section 1.17(a)(1)-(5) (extension fees pursuant to Section 1.136(a).
- ☐ 37 C.F.R. Section 1.17 (application processing fees)

**NOTE:** *"A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under Section 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in Section 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. Section 1.136(a)(3).*

**NOTE:** *Section 1.311(b) provides that an authorization to charge the issue fee (§ 1.18) to a deposit account may be filed in an individual application only after the mailing of the notice of allowance. Accordingly, general authorizations to pay fees and specific authorizations to pay the issue fee that are filed prior to the mailing of a notice of allowance will generally not be treated as requesting payment of the issue fee and will not be given effect to act as a reply to the notice of allowance. Applicant, when paying the issue fee, should submit a new authorization to charge fees, such as by completing box 6b on the current PTOL-85B form. Where no reply to the notice of allowance is received, the application will stand abandoned notwithstanding the presence of general authorizations to pay fees or a specific authorization to pay the issue fee that were submitted prior to mailing of the notice of allowance. Where an attempt is made to pay the issue fee but an incorrect amount is submitted, § 1.311(b)(1), or where the Office's issue fee transmittal form (currently PTOL-85(B)) is completed by applicant and submitted, § 1.311(b)(2), in reply to a notice of allowance, an exception will be made. Such submissions will operate as a request to charge the issue fee to any deposit account identified in a previously filed (i.e., submitted prior to the mailing of the notice of allowance) authorization to charge fees, and will be allowed to act as payment of the correct issue fee. § 1.311(b). See also the change to § 1.26(b). Notice of September 8, 2000, Fed. Reg. 54603-54683, at 54646 and 54647.*

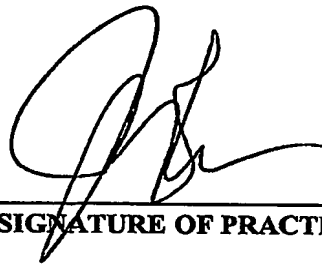
**NOTE:** 37 C.F.R. Section 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . . issue fee." From the wording of 37 C.F.R. Section 1.28(b), (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

**16. Instructions as to Overpayment**

**NOTE:** "... Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. Section 1.26(a).

☐ Credit Account No. 12-0425.

☐ Refund



**SIGNATURE OF PRACTITIONER**

JULIAN H. COHEN

(type or print name of practitioner)

Reg. No. 20,302

Tel. No.: (212)708-1887

P.O. Address

Customer No.: 00140

c/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, N.Y. 10023



**00140**

PATENT TRADEMARK OFFICE

**[X] Incorporation by reference of added pages**

*(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)*

**[X] Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed**

Number of pages added 8

**[ ] Plus added pages deleting names of inventor(s) named on prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application.**

Number of pages added                     

**[ ] Statement Where No Further Pages Added**

*(if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item)*

**[ ] This transmittal ends with this page.**

(New Application Transmittal—page 15 of 15) 4-1



**ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF  
PRIOR U.S. APPLICATION(S) CLAIMED**

NOTE: See 37 CFR 1.78.

**17. Relate Back**

**WARNING:** *If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.*

*(complete the following, if applicable)*

[ ] **A separate Preliminary Amendment amends the specification by inserting, before the first line, the following paragraph:**

**A. 35 U.S.C. 119(e)**

NOTE: 37 C.F.R. § 1.78(a)(4) and (5):

*"(4) A nonprovisional application, other than for a design patent, or an international application designating the United States of America may claim an invention disclosed in one or more prior-filed provisional applications. In order for an application to claim the benefit of one or more prior-filed provisional applications, each prior-filed provisional application must name as an inventor at least one inventor named in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later filed application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior-filed provisional application must be entitled to a filing date as set forth in § 1.53(c), and the basic filing fee set forth in § 1.16(k) must be paid within the time period set forth in § 1.53(g).*

*"(5)(i) Any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed provisional applications must contain or be amended to contain a reference to each such prior-filed provisional application, identifying it by the provisional application number (consisting of series code and serial number).*

*(ii) This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed provisional application. IF the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national state commenced under 35 U.S.C. 371(b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed provisional application. These time periods are not extendable. Except as provided in paragraph (a)(6) of this section, the failure to timely submit the reference is considered a waiver of any benefit under 35 U.S.C. 119(e) to such prior-filed provisional application. The time periods in this paragraph do not apply if the later-filed application is:*

(A) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or

(B) A nonprovisional application which entered the national stage after compliance with 35 U.S.C. 371 from an international application filed under 35 U.S.C. 363 before November 29, 2000.

(iii) If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence following the title."

[X] "This application claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S):

FILING DATE

60 / NOT YET KNOWN  
60 / 571.438  
         /                     

SEPTEMBER 8, 2004  
MAY 14, 2004  
                                

and incorporates the same by reference."

**WARNING:** 37 C.F.R. § 1.78(5)(iv): "(iv) If the prior-filed provisional application was filed in a language other than English and an English-language translation of the prior-filed provisional application and a statement that the translation is accurate were not previously filed in the prior-filed provisional application or the later-filed nonprovisional application, applicant will be notified and given a period of time within which to file an English-language translation of the non-English-language prior-filed provisional application and a statement that the translation is accurate. In a pending nonprovisional application failure to timely reply to such a notice will result in abandonment of the application."

#### Language of Prior Filed Provisional Application

(Supply information for each provisional the benefit of which is being claimed)

The above identified prior filed provisional application whose benefit is being claimed

[X] was filed in the English language,

[ ] was filed in a language other than English and an English translation along with a statement that the translation is accurate was filed in the provisional application, or

[ ] was filed in language other than English and an English translation along with a statement that the translation is accurate is filed herewith.

#### B. 35 U.S.C. 120, 121 and 365(c)

**WARNING:** The applicable provisions for the time and manner of claiming the benefit of a prior U. S. application filing date are set forth in 37 C.F.R. § 1.78(a)(1) and (2) as follows:

"(a)(1) A nonprovisional application or international application designating the United States of America may claim an invention disclosed in one or more prior-filed copending nonprovisional applications or international applications designating the United States of America. In order for an application to claim the benefit of a prior-filed copending nonprovisional application or international application designating the United States of America, each prior-filed application must name as an inventor at least one inventor named in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later-filed application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior-filed application must be:

(i) An international application entitled to a filing date in accordance with PCT Article 11 and designating

the United States of America; or

(ii) Complete as set forth in § 1.51(b); or

(iii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and include the basic filing fee set forth in § 1.16; or

(iv) Entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(f) within the time period set forth in § 1.53(f).

(2)(i) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross references to other related applications may be made when appropriate (see § 1.14).

(ii) This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. If the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed application. These time periods are not extendable. Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (a)(2)(i) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior-filed application. The time periods in this paragraph do not apply of the later-filed application is:

(A) An application for a design patent;

(B) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or

(C) A nonprovisional application which entered the national stage after compliance with 35 U.S.C. 371 from an international application filed under 35 U.S.C. 363 before November 29, 2000.

(iii) If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence following the title.

(iv) The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior-filed application. The identification of an application by application number under this section is the identification of every application assigned that application number necessary for a specific reference required by 35 U.S.C. 120 to every such application assigned that application number."

☒ "This application is a

☐ continuation

☒ continuation-in-part

☐ divisional

of copending

☒ application number 10/838,648 filed on May 3, 2004 and U.S. Serial No. 10/753,424 filed January 9, 2004

[ ] International Application \_\_\_\_\_ filed on \_\_\_\_\_, which designated the U.S.,  
claims the benefit thereof and incorporates the same by reference."

**NOTE:** The proper reference to a prior filed PCT application that entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application that designated the U.S.

**NOTE:** (1) Where the application being transmitted adds subject matter to the International Application, then the filing can be as a continuation-in-part or (2) if it is desired to do so for other reasons then the filing can be as a continuation.

[ ] "The nonprovisional application designated above, namely application \_\_\_\_\_ / \_\_\_\_\_, filed \_\_\_\_\_, claims the benefit of U.S. Provisional Application(s) No(s).:

**APPLICATION NO(S).:**

**FILING DATE**

\_\_\_\_\_/

\_\_\_\_\_/

\_\_\_\_\_/

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

and incorporates the same by reference"

### C. Publication of International Application-Provisional Application

**NOTE:** 35 U.S.C. 154 Contents and term of patent; provisional rights

**(d)(4) REQUIREMENTS FOR INTERNATIONAL APPLICATIONS—**

(A) **EFFECTIVE DATE**—The right under paragraph (1) to obtain a reasonable royalty based upon the publication under the treaty defined in section 351(a) of an international application designating the United States shall commence on the date on which the Patent and Trademark Office receives a copy of the publication under the treaty of the international application, or, if the publication under the treaty of the international application is in a language other than English, on the date on which the Patent and Trademark Office receives a translation of the international application in the English language.

**The international application corresponding to the instant application**

[ ] was

[ ] was not

**published under PCT Article 21(2) in the English language.**

[ ] An English translation of the international application is attached.

## 18. Relate Back—35 U.S.C. 119 Priority Claim for Prior Application

NOTE: 37 C.F.R. § 1.55 Claim for foreign priority.

*"(a) An applicant in a nonprovisional application may claim the benefit of the filing date of one or more prior foreign applications under the conditions specified in 35 U.S.C. 119(a) through (d) and (f), 172, and 365(a) and (b).*

*(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. This time period is not extendable. The claim must identify the foreign application for which priority is claimed, as well as any foreign application for the same subject matter and having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time period in this paragraph does not apply to an application for a design patent.*

*(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT."*

*(2) The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) or PCT Rule 17 must, in any event, be filed before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in § 1.17(i), but the patent will not include the priority claim unless corrected by a certificate of correction under 35 U.S.C. 255 and § 1.323.*

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17B, in turn itself claim(s) foreign priority(ies) as follows:

| Country | Appln. no. | Filed |
|---------|------------|-------|
|---------|------------|-------|

| Country | Appln. no. | Filed |
|---------|------------|-------|
|---------|------------|-------|

The certified copy(ies) has (have)

☐ been filed on \_\_\_\_\_, in prior U. S. national (not PCT) application \_\_\_\_\_, which was filed on \_\_\_\_.

☐ is (are) attached.

☐ will follow.

**WARNING:** *The certified copy of the priority application that may have been communicated to the PTO by the International Bureau may not be relied on without any need to file a certified copy of the priority application in the continuing application. This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. serial number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore, such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the Continuing Application are substantial. Accordingly, the priority documents in folders of international applications that have not entered the national stage may not be relied on. Notice of April 28, 1987 (1079 O.G. 32 to 46).*

**19. Maintenance of Copendency of Prior Application**

**NOTE:** *The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).*

**A. ☐ Extension of time in prior application**

☐ A petition and fee extends the term in the pending prior application until \_\_\_\_\_.

☐ A copy of the petition filed in prior application is attached.

**B. ☐ Conditional Petition for Extension of Time in Prior Application**

☐ A conditional petition for extension of time is being filed in the pending prior application.

☐ A copy of the conditional petition filed in the prior application is attached.

**C. ☐ No extension is necessary in Prior Application**

☐ Issue Fee paid \_\_\_\_\_

**20. Further Inventorship Statement Where Benefit of Prior Application(s) Claimed**

*(complete applicable item (a), (b) and/or (c) below)*

(a) ☐ This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are

☐ the same.

☐ less than those named in the prior application. It is requested that the following inventor(s) identified for the prior application be deleted:

---

*(type name(s) of inventor(s) to be deleted)*

(b) ☐ This application discloses and claims additional disclosure and a new declaration or oath is being filed. With respect to the prior application, the inventor(s) in this application are

☐ the same.

☐ the following additional inventor(s) have been added:

---

*(type name(s) of inventor(s) to be added)*

(c) ☐ The inventorship for all the claims in this application are

☐ the same.

☐ not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made

☐ is submitted.

☐ will be submitted.

**21. Abandonment of Prior Application (if applicable)**

☐ Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make this application copending with said prior application.

**NOTE:** According to the Notice of May 13, 1983 (103, TMOG 6-7), the filing of a continuation or continuation-in-part application is a proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.

## 22. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

**WARNING:** *"The claims of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been properly finally rejected on the grounds of art of record in the next Office action if they had been entered in the earlier application." MPEP, § 706.07(b).*

**NOTE:** *Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.*

*(check the next item, if applicable)*

- ☐ There is provided herewith a Petition To Suspend Prosecution for the Time Necessary to File An Amendment (New Application Filed Concurrently)

## 23. NOTIFICATION IN PARENT APPLICATION OF THIS FILING

- ☐ A notification of the filing of this  
*(check one of the following)*

☐ continuation

☐ continuation-in-part

☐ divisional

is being filed in the parent application, from which this application claims priority under 35 U.S.C. § 120.



52685s3

**PRESSURE-PROPELLED SYSTEM FOR BODY LUMEN****CROSS-REFERENCES TO RELATED APPLICATIONS**

The present application is a continuation-in-part of:

- (a) US Patent Application 10/838,648 to Gross et al., filed May 3, 2004, entitled,  
5 "Pressure-propelled system for body lumen," and  
(b) US Patent Application 10/753,424 to Gross et al., filed January 9, 2004,  
entitled, "Pressure-propelled system for body lumen."

The present application claims priority from:

- (a) a US provisional patent application to Cabiri et al., filed September 8, 2004,  
10 entitled, "Mechanical aspects of pressure-propelled system for body lumen," and  
(b) US Provisional Patent Application 60/571,438 to Dotan et al., filed May 14,  
2004, entitled, "Omnidirectional and forward-looking imaging device."

All of the above-mentioned applications are assigned to the assignee of the present application and are incorporated herein by reference.

15 **FIELD OF THE INVENTION**

The present invention relates generally to a pressure-propelled system, suitable for imaging body lumens, such as the gastrointestinal (GI) tract.

**BACKGROUND OF THE INVENTION**

- Many imaging devices are known for producing medical images of body lumens,  
20 such as the gastrointestinal (GI) tract. For example, endoscopy is widely used for observing, photographing tissue, and taking specimens from lesions and the like. In a conventional method of examining a colon using an endoscope, for example, the endoscope is typically manually inserted into the colon. In this manual technique, patients may often complain of abdominal pain and distention because the colon is  
25 extended or excessively dilated, thereby necessitating stopping the endoscopic procedure. Furthermore, it is not unusual for the colon to bleed and be accidentally perforated. Insertion of an endoscope through the sigmoid colon and into the descending colon, or through the splenic flexure, the transverse colon, the hepatic flexure or parts affected by previous operations may also be accompanied with difficulty. Because of these reasons, a

52685s3

colonoscopy is typically performed by a relatively small number of skilled practitioners, and the rate of patient pain and discomfort is high.

US Patent 5,337,732 to Grundfest et al., whose disclosure is incorporated herein by reference, describes a robot for performing endoscopic procedures, which includes a plurality of segments attached to each other through an articulated joint. Actuators can move the segments together and apart and change their angular orientation to allow the robot to move in an inchworm or snake-like fashion through a cavity or lumen within a patient. Inflatable balloons around the segments inflate to brace a temporarily stationary segment against the lumen walls while other segments move. A compressed gas line attached to the back segment provides compressed gas to inflate the balloons and optionally to drive the actuators. The lead segment includes a television camera and biopsy arm or other sensors and surgical instruments.

US Patent Application Publication 2003/0168068 to Poole and Young, whose disclosure is incorporated herein by reference, describes a method for lining a body cavity with a liner that contains two chambers by (a) selectively controlling fluid pressure in a first of the chambers so as cause the first chamber to evert and advance into said body cavity, and (b) selectively controlling fluid pressure in a second of said chambers to control the stiffness of the liner.

US Patent Application Publication 2003/0105386 and US Patent 6,485,409 to Voloshin et al., whose disclosures are incorporated herein by reference, describe endoscopic apparatus comprising an inflatable sleeve, wherein inflating the sleeve causes an endoscope to be advanced into the colon.

US Patent Application Publication 2002/0107478 to Wendlandt, whose disclosure is incorporated herein by reference, describes a self-propelled catheter, wherein pressurizing an everting tube coupled to the catheter advances the catheter into the body.

US Patent 6,702,735 to Kelly, whose disclosure is incorporated herein by reference, describes a device for moving a tool along a passage. The tool is coupled to an inflatable sheath, such that as the sheath is inflated it extends into the passage and carries the tool along.

US Patent 5,259,364 to Bob, et al., whose disclosure is incorporated herein by reference, describes an endoscopic device comprising a flexible eversion tube, wherein inflating the eversion tube causes an endoscope to be advanced into a body cavity.

5 US Patent 4,403,985 to Boretos, whose disclosure is incorporated herein by reference, describes a catheter containing ports near its distal end through which high pressure fluid is forced to advance and steer the catheter.

US Patent 4,176,662 to Frazer, whose disclosure is incorporated herein by reference, describes an endoscope having a propulsion mechanism and at least one transmitter at the distal end transmitting bursts of energy waves for tracking the position  
10 of the distal end. The propulsion mechanism consists of two radially expandable bladders separated by an axially expandable bellows with only the forward bladder attached to the distal end so that by expanding and contracting them in proper sequence, propulsion of the endoscope is achieved.

US Patent 4,148,307 to Utsugi, whose disclosure is incorporated herein by  
15 reference, describes a tubular medical instrument having at least one cuff assembly including two cuffs disposed on the circumference of a flexible sheath, spaced at prescribed intervals and made expansible only in a radial direction of the flexible sheath, and a deformable propellant cuff having a doubled-back section, disposed also on the circumference of the sheath between the two cuffs. When air is introduced into, or drawn  
20 from, the three cuffs selectively, the flexible sheath automatically advances step-by-step in a human body cavity.

US Patent 5,906,591 to Dario et al., whose disclosure is incorporated herein by reference, describes an endoscopic robot, adapted to be inserted into a body cavity of a patient and to be advanced therein using "inchworm-like" motion.

25 US Patent 6,007,482 to Madni et al., whose disclosure is incorporated herein by reference, describes an endoscope having a pair of telescoping sections at its distal end, one of which carries a camera, and which are alternately actuated to provide movement through a body passageway by a Bowden type of cable. Respectively attached to the two cylindrical sections are inflatable bladders which provide for the movement.

30 US Patent 5,662,587 to Grundfest et al., whose disclosure is incorporated herein by reference, describes an endoscopic robot having a plurality of segments attached to

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each other. Traction segments embrace the walls of a body lumen. Other segments include actuators that cause the endoscope to locally deform its shape via bending, extending, or some combination of bending and extension. A method is provided to sequence the action of the segments to cause "inchworm-like" or "snake-like" locomotion, or a combination of them through a curved and flexible lumen. A compressed gas line attached to the back segment provides compressed gas for insufflation of the lumen, and can optionally be used to drive the actuators that control the operation of the endoscope segments.

US Patent 4,690,131 to Lyddy, Jr. et al., whose disclosure is incorporated herein by reference, describes a combination of elements adapted to be used with an endoscope, and capable of at least partially extending with the instrument into the lumen of a tubular body part, such as the large intestine. A sheath is adapted to be mounted on the endoscope. The endoscope and sheath are provided with selectively inflatable cuffs movable with respect to one another by axially sliding the sheath on the endoscope.

US Patent 4,040,413 to Ohshiro, which is incorporated herein by reference, describes an endoscope comprising a tube having one or more inflatable balloons on an outer surface thereof. A fiber optic bundle passes through the tube to a distal flexible portion of the tube, for viewing an interior of a body cavity. When only one balloon is provided, the balloon is provided on one side of the tube near the end thereof to enlarge the space within a body cavity in one direction so that there is sufficient space in this direction for the flexible portion of the tube to bend in this direction, and to thereby obtain a large field of view. When more than one balloon is provided, one of the balloons is selectively inflated to enlarge the space within the body cavity in the desired direction. In an embodiment, an outer sleeve is provided around the tube with balloons on the outer face thereof and is made slidable with respect to the tube. The outer sleeve and the tube are inserted into the body cavity by alternately inflating the balloons on the outer sleeve and those on the tube to facilitate the insertion thereof into the body cavity.

US Patent 6,503,192 to Ouchi, which is incorporated herein by reference, describes an insertion facilitating device for an intestinal endoscope. The device has a cylindrical body in which an insertion portion of the endoscope is inserted while holding an anal sphincter of a patient in an open position. The cylindrical body is provided at one end thereof with a conical opening. In an embodiment, the cylindrical body is provided

on its inner surface with a pressure leakage prevention ring made of a sponge material, for preventing leakage of internal air of the patient's body.

US Patent Application Publication 2003/0083547 to Hamilton et al., which is incorporated herein by reference, describes methods and apparatus for inhibiting longitudinal expansion of a body portion of an endoscopic sheath during inflation of an inflatable member. In one embodiment, a sheath assembly includes a body portion adapted to encapsulate a distal end of an insertion tube, and an inflatable member coupled to the body portion and adapted to be inflated radially outwardly from the body portion. The sheath assembly further includes an expansion-inhibiting mechanism coupled to at least one of the inflatable member and the body portion. The expansion-inhibiting mechanism is described as inhibiting longitudinal expansion of the body portion during inflation of the inflatable member. The expansion-inhibiting mechanism may comprise, for example, a non-compliant member, a longitudinally-stretched portion, a reinforcing spring member, a pressure relief device, or a suitable detent mechanism.

PCT Publication WO 04/069057 to Gobel, which is incorporated herein by reference, describes a device for use in healing processes, comprising a flexible double-walled inflatable tube segment which encloses a hollow space.

US Patent Application Publication 2003/0000526 to Gobel, which is incorporated herein by reference, describes techniques for controlling the breathing gas flow of a ventilator for assisted or controlled ventilation of a patient as a function of the tracheobronchial airway pressure of the patient. The techniques include introducing a ventilator tube, such as a tracheal tube or tracheostomy tube, into the trachea. The tube is subjected to breathing gas, and is equipped with an inflatable cuff and at least one lumen that is continuous from the distal end of the tube to the proximal end of the tube. The tube is adapted to detect the airway pressure by continuous or intermittent detection and evaluation of the intra-cuff pressure prevailing in the cuff of the tube. The breathing gas flow of the ventilator is controlled as a function of the intra-cuff pressure detected.

PCT Publication WO 03/045487 to Gobel, which is incorporated herein by reference, describes a bladder catheter for transurethral introduction into the urinary bladder by the urethrae, consisting of an elastic catheter shank with a fillable balloon element secured thereto and connected to a filling channel incorporated into the wall of

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the catheter shank. The balloon element and the catheter shank are made of polyurethane, a polyurethane-polyvinylchloride mixture, or similar polyurethane-based material.

### SUMMARY OF THE INVENTION

Some embodiments of the present invention provide an imaging system which is propelled by fluid pressure through a body lumen, such as the gastrointestinal (GI) tract. Embodiments of the invention are described hereinbelow with reference to the GI tract, but it is understood that these embodiments are not limited to use in the GI tract, and may be used for other body lumens as well. Unlike the prior art, which may inflate and anchor balloons and similar devices to the GI tract wall in an attempt to overcome the low friction of the GI tract, these embodiments of the present invention utilize the very low friction environment of the GI tract to propel the imaging system, typically with no need for anchoring.

There is thus provided, in accordance with an embodiment of the present invention, a system including a guide member at least partially insertable into a proximal opening of a body lumen, the guide member including a first passageway connectable to a source of fluid pressure, an elongate carrier arranged for sliding movement through the guide member, and a piston head mounted on the carrier, wherein a greater fluid pressure acting on a proximal side of the piston head than on a distal side of the piston head propels the piston head and the carrier in a distal direction in the body lumen.

The system of this embodiment of the invention may have different features. For example, the piston head may be inflatable. The carrier may include a second passageway in fluid communication with the piston head, which may be connected to a source of fluid pressure for inflating the piston head. A vent tube may pass through the piston head, having an opening distal to the piston head through which fluid may be vented to the outside. An image-capturing device may be mounted on the carrier, such as distal to the piston head. A power supply tube may pass through the carrier and may be connected to the image-capturing device. A fluid supply tube may pass through the carrier and may be connected to a fluid source.

In accordance with an embodiment of the present invention, an auxiliary piston head may be mounted on the carrier proximal to the first-mentioned piston head. The auxiliary piston head, which may be inflatable, may be fixed axially to the carrier at a fixed or variable distance from the first-mentioned piston head. The carrier may include a

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third passageway in fluid communication with the auxiliary piston head, which may be connected to a source of fluid pressure for inflating the auxiliary piston head.

There is therefore provided, in accordance with an embodiment of the present invention, apparatus for use with a biologically-compatible-fluid pressure source,  
5 including:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

a distal piston head coupled to a distal portion of the carrier and adapted to:  
be in direct contact with a wall of the lumen when the carrier is  
10 inserted into the lumen,

be advanced distally through the body lumen in response to pressure from the fluid pressure source, and

facilitate passage of fluid out of the lumen from a site within the lumen distal to the piston head.

15 In an embodiment, an outer surface of the piston head in contact with the wall of the lumen includes a low friction coating suitable for facilitating sliding of the piston head against the wall of the lumen.

In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the piston head is adapted to be in direct contact with a wall of the GI tract when the carrier is  
20 inserted into the GI tract. For example, the GI tract may include a colon, and the piston head may be adapted to be in direct contact with a wall of the colon when the carrier is inserted into the colon.

In an embodiment, the apparatus includes a vent tube, and the piston head is adapted to facilitate the passage of the fluid out of the lumen through the vent tube. For  
25 some applications, the vent tube is shaped to define an inner diameter thereof that is between 1 and 5 millimeters, e.g., between 1 and 3 millimeters. In an embodiment, the vent tube is adapted to passively permit the passage of the fluid out of the lumen. Alternatively, the vent tube is adapted to be coupled to a suction source, whereby to actively facilitate the passage of the fluid out of the lumen. For example, the vent tube  
30 may be adapted to be coupled to the suction source such that during operation of the apparatus, a pressure distal to the piston head is between -5 millibar and +15 millibar.



In an embodiment, the piston head is adapted to be inflated so as to attain and maintain the direct contact with the wall of the colon.

For some applications:

(i) the apparatus includes an auxiliary piston head, coupled to the carrier at a position proximal to the distal piston head,

(ii) the auxiliary piston head is adapted to be inflated so as to attain and maintain direct contact with the wall of the colon, and

(iii):

(a) at at least one time while the carrier is within the body lumen, the distal piston head is adapted to be in a state of being already deflated at least in part simultaneously with the auxiliary piston head being already inflated and being advanced distally through the colon in response to pressure from the fluid pressure source, and

(b) at at least one other time while the carrier is within the body lumen, the auxiliary piston head is adapted to be in a state of being already deflated at least in part simultaneously with the distal piston head being already inflated and being advanced distally through the colon in response to pressure from the fluid pressure source.

In an embodiment, the piston head is adapted to be intermittently deflated at least in part, while in the colon, whereby to facilitate the passage of the fluid out of the lumen from the site within the lumen distal to the piston head.

In an embodiment, the apparatus includes a piston-head-pressure sensor, adapted to sense a pressure within the piston head. Alternatively or additionally, the apparatus includes a distal pressure sensor, adapted to sense a pressure within the colon distal to the piston head. Further alternatively or additionally, the apparatus includes a proximal pressure sensor, adapted to sense a pressure within the colon proximal to the piston head. For some applications, one, two, or three of these sensors are provided.

In an embodiment, the apparatus includes:

a pressure sensor, adapted to measure a first pressure associated with operation of the apparatus; and

a control unit, adapted to regulate a second pressure associated with operation of the apparatus responsive to the measurement of the pressure sensor.

For example, the pressure sensor may be adapted to measure a pressure selected from the list consisting of: a pressure distal to the piston head, a pressure proximal to the piston head, and a pressure within the piston head.

5 In an embodiment, the control unit is adapted to regulate the pressure being measured by the pressure sensor. Alternatively, the control unit is adapted to regulate a pressure other than that being measured by the pressure sensor.

In an embodiment, the piston head is shaped to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

For some applications:

10 (a) a volume of a first one of the lobes is adapted to decrease in response to a constriction of the colon adjacent thereto,

(b) a volume of a second one of the lobes is adapted to remain constant in the absence of a change in colon diameter adjacent thereto, even if the volume of the first lobe is decreased, and/or

15 (c) a pressure within the first and second lobes is equal in steady state, regardless of the decrease in volume of the first lobe.

In an embodiment, the piston head is adapted to be at an inflation pressure between 10 and 60 millibar during advancement through the colon (e.g., 20-50 millibar, or 30-45 millibar). Alternatively or additionally, the piston head is adapted to advance  
20 through the colon in response to a pressure from the fluid pressure source that is between 30% and 100% of the inflation pressure. For example, the piston head may be adapted to advance through the colon in response to a pressure from the fluid pressure source that is between 50% and 100% of the inflation pressure (e.g., between 50% and 80% of the inflation pressure).

25 In an embodiment, the piston head is shaped to define a distally-narrowing portion, and is adapted to be inserted into the colon such that a tip of the distally-narrowing portion points in a distal direction when the piston head is in the colon. For some applications, a proximal base of the distally-narrowing portion has a characteristic fully-inflated diameter that is larger than a diameter of at least a part of the colon through  
30 which the distally-narrowing portion is adapted to pass, whereby the base of the distally-narrowing portion does not inflate fully when the base is in that part of the colon.

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There is further provided, in accordance with an embodiment of the present invention, a method, including:

- placing a distal piston head in direct contact with a wall of a body lumen;
- applying fluid pressure to the distal piston head to advance the piston head distally
- 5 through the body lumen; and
- facilitating passage of fluid out of the lumen from a site within the lumen distal to the piston head.

In an embodiment, the method includes applying a low friction coating to an outer surface of the piston head intended for contact with the wall of the lumen, the low friction coating being suitable for facilitating sliding of the piston head against the wall of the lumen.

In an embodiment, the lumen includes a gastrointestinal (GI) tract, and placing the piston head includes placing the piston head in direct contact with a wall of the GI tract. In an embodiment, the GI tract includes a colon, and placing the piston head includes placing the piston head in direct contact with a wall of the colon.

In an embodiment, facilitating the passage of the fluid includes facilitating the passage of the fluid out of the lumen through a vent tube extending from the site distal to the piston head to a site outside of the lumen. For some applications, facilitating the passage of the fluid includes passively permitting the passage of the fluid through the vent tube and out of the lumen. Alternatively, facilitating the passage of the fluid includes actively removing the fluid from the lumen. For example, actively removing the fluid may include applying to the site distal to the piston head a pressure between -5 millibar and +15 millibar.

In an embodiment, placing the piston head in direct contact with the wall includes inflating the piston head to an extent sufficient to attain and maintain the direct contact with the wall of the colon.

In an embodiment, the method includes:

- placing an auxiliary piston head proximal to the distal piston head;
- inflating the auxiliary piston head to an extent sufficient to attain and maintain
- 30 direct contact with the wall of the colon;

at at least one time while the distal piston head is within the body lumen, deflating the distal piston head at least in part, such that at a post-distal-piston-head-deflation time

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when the distal piston head is in a state of being already deflated at least in part, the auxiliary piston head is inflated and advancing distally through the colon in response to the applied fluid pressure; and

at least one other time while the distal piston head is within the body lumen,  
5 deflating the auxiliary piston head at least in part, such that at a post-auxiliary-piston-head-deflation time when the auxiliary piston head is in a state of being already deflated at least in part, the distal piston head is inflated and advancing distally through the colon in response to the applied pressure.

In an embodiment, facilitating the passage of the fluid out of the lumen includes  
10 intermittently deflating the piston head at least in part.

In an embodiment, the method includes sensing a pressure within the piston head, within the colon distal to the piston head, and/or within the colon proximal to the piston head.

In an embodiment, the method includes:  
15 sensing a first pressure associated with performing the method; and  
regulating a second pressure associated with performing the method, responsive to sensing the first pressure.

For example, sensing the first pressure may include sensing a pressure selected from the list consisting of: a pressure distal to the piston head, a pressure proximal to the  
20 piston head, and a pressure within the piston head.

For some applications, regulating the second pressure includes regulating the first pressure. Alternatively, regulating the second pressure does not include regulating the first pressure.

In an embodiment, inflating the piston head includes inflating the piston head at  
25 an inflation pressure between 10 and 60 millibar. Alternatively or additionally, applying the fluid pressure includes setting the fluid pressure to between 30% and 100% of the inflation pressure (e.g., between 50% and 100% of the inflation pressure, or between 50% and 80% of the inflation pressure).

In an embodiment, inflating the piston head includes inflating the piston head at  
30 an inflation pressure between 20 and 50 millibar (e.g., between 30 and 45 millibar).

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There is therefore provided, in accordance with an embodiment of the present invention, apparatus for use with a biologically-compatible-fluid pressure source, including:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen;

a distal piston head coupled to a distal portion of the carrier and adapted to:

be in direct contact with a wall of the lumen after the carrier has been inserted into the lumen,

be advanced distally through the body lumen in response to pressure from the fluid pressure source, and

facilitate passage of fluid out of the lumen from a site within the lumen distal to the piston head; and

an optical system having distal and proximal ends, and including:

an image sensor, positioned at the proximal end of the optical system;

an optical member having distal and proximal ends, and shaped so as to define a lateral surface, at least a distal portion of which is curved, configured to provide omnidirectional lateral viewing; and

a convex mirror, coupled to the distal end of the optical member, wherein the optical member and the mirror have respective rotational shapes about a common rotation axis.

For some applications, the convex mirror is shaped so as define an opening through which distal light can pass.

There is also provided, in accordance with an embodiment of the present invention, apparatus for use with a biologically-compatible-fluid pressure source, including:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen;

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an inflatable distal piston head coupled to a distal portion of the carrier, the distal piston head shaped so as to define a proximal lobe and a distal lobe in fluid communication with each other, the distal piston head adapted to:

5 be inflated so as to attain direct contact with a wall  
of the lumen after the carrier has been inserted into the  
lumen, and

be advanced distally through the body lumen in  
response to pressure from the fluid pressure source; and  
a flexible vent tube, passing through the proximal and distal lobes of the piston  
10 head, and opening to a site within the lumen distal to the piston head, and adapted to  
facilitate passage of fluid from the site.

There is further provided, in accordance with an embodiment of the present invention, apparatus including:

15 an elongate carrier, adapted to be inserted through a proximal opening of a body  
lumen;

a balloon coupled to a distal portion of the carrier and adapted to be in direct  
contact with a wall of the lumen after the carrier has been inserted into the lumen; and  
a hydrophilic substance disposed at an external surface of the balloon.

20 There is still further provided, in accordance with an embodiment of the present  
invention, apparatus including:

an elongate carrier, adapted to be inserted through a proximal opening of a body  
lumen; and

a balloon coupled to a distal portion of the carrier and adapted to be in direct  
contact with a wall of the lumen after the carrier has been inserted into the lumen, the  
25 balloon having a characteristic thickness of no more than 20 microns.

For some applications, the balloon has a characteristic thickness of no more than  
10 microns.

There is additionally provided, in accordance with an embodiment of the present  
invention, apparatus for use with a biologically-compatible-fluid pressure source,  
30 including:

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an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

a distal piston head coupled to a distal portion of the carrier and adapted to:

5 be in direct contact with a wall of the lumen after the carrier has been inserted into the lumen, and

be withdrawn proximally through the body lumen in response to pressure from the fluid pressure source.

For some applications, the carrier is adapted to facilitate passage of fluid out of the lumen from a site within the lumen proximal to the piston head.

10 There is yet additionally provided, in accordance with an embodiment of the present invention, apparatus for use with an elongate carrier for insertion through a proximal opening of a body lumen, the apparatus including:

an annular balloon, shaped so as to form an opening therethrough for insertion of the carrier, the balloon expandable to form a seal between the balloon and a wall of the  
15 body lumen in a vicinity of the proximal opening;

first and second fluid pressure sources;

a first tube, coupled between the first pressure source and an interior of the balloon; and

a second tube, coupled between the second pressure source and an interior of the  
20 lumen distal to the annular balloon.

For some applications, at least one of the first and second pressure sources is adapted to be positioned outside the body lumen.

There is also provided, in accordance with an embodiment of the present invention, apparatus including:

25 an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

an inflatable cuff, shaped so as to define an opening therethrough through which the carrier can be inserted, the cuff adapted to form a seal with a wall of the body lumen when the cuff is in an inflated state in a vicinity of the proximal opening.

30 There is further provided, in accordance with an embodiment of the present invention, apparatus for use with a fluid source, the apparatus including:

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an elongate carrier, adapted to be inserted through a proximal opening of a body lumen;

an image-capturing device, fixed to the carrier in a vicinity of a distal end of the carrier; and

5 at least one fluid supply tube coupled to the carrier, the tube coupled to the fluid source,

wherein the distal end of the carrier is shaped so as to define one or more openings in fluid communication with the tube, the openings oriented so as to spray at least a portion of the image-capturing device when fluid is provided by the fluid source.

10 There is still further provided, in accordance with an embodiment of the present invention, apparatus for use in a body lumen having a proximal opening and a wall, the apparatus including:

an elongate carrier, adapted to be inserted through the proximal opening of the body lumen;

15 an image-capturing device, fixed in a first vicinity of a distal end of the carrier, and adapted to provide omnidirectional lateral viewing; and

an inflation element, fixed in a second vicinity of the distal end, and adapted to increase a diameter of the carrier in the second vicinity to an extent sufficient to position the image-capturing device a distance from the wall sufficient to enable omnidirectional  
20 focusing of the image-capturing device.

There is additionally provided, in accordance with an embodiment of the present invention, apparatus for use in a body lumen having a proximal opening, the apparatus including:

first and second fluid pressure sources;

25 an elongate carrier, adapted to be inserted through the proximal opening of the body lumen;

a distal inflatable piston head coupled to a distal portion of the carrier, and adapted to be in direct contact with a wall of the lumen after the carrier has been inserted into the lumen;

30 a first passageway in fluid communication with the first pressure source and a proximal portion of the lumen proximal to the piston head;



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a second passageway in fluid communication with the second pressure source and the piston head;

first and second pressure sensors, adapted to measure pressure in the proximal portion of the lumen, and in the piston head, respectively; and

5 a control unit, adapted to cause the piston head to be advanced distally in the lumen by:

while the first pressure source applies a pressure to the proximal portion of the lumen,

10 driving the second pressure source to regulate a pressure in the piston head to be equal to the pressure in the proximal portion of the lumen plus a positive value.

For some applications, the apparatus includes a third passageway in fluid communication with a portion of the lumen distal to the piston head and a site outside the lumen.

15 There is yet additionally provided, in accordance with an embodiment of the present invention, apparatus for use with a biologically-compatible-fluid pressure source, including:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen;

20 a piston head coupled to a distal portion of the carrier and adapted to:

form a pressure seal with a wall of the lumen after the carrier has been inserted into the lumen, and

be advanced distally through the body lumen in response to pressure from the fluid pressure source,

25 the apparatus being configured to facilitate distal advancement of the piston head by facilitating passage of fluid out of the lumen from a site within the lumen distal to the piston head; and

30 an optical system, coupled to the carrier in a vicinity of the distal portion, the optical system having distal and proximal ends, and including:

an image sensor, positioned at the proximal end of the optical system;

an optical member having distal and proximal ends,  
and shaped so as to define a lateral surface, at least a distal  
portion of which is curved, configured to provide  
omnidirectional lateral viewing; and

- 5           a convex mirror, coupled to the distal end of the  
optical member, wherein the optical member and the mirror  
have respective rotational shapes about a common rotation  
axis.

10           In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the carrier  
is adapted to be inserted through the proximal opening of the GI tract. In an embodiment,  
the GI tract includes a colon, and the carrier is adapted to be inserted through the  
proximal opening of the colon.

In an embodiment, the piston head is adapted to be in direct contact with the wall  
of the GI tract after the carrier has been inserted into the GI tract.

- 15           For some applications, the convex mirror is shaped so as to define an opening  
through which distal light can pass. For some applications, the optical member is shaped  
so as to define a distal indentation in the distal end of the optical member. For some  
applications, the optical member is shaped so as to define a proximal indentation in the  
proximal end of the optical member. For some applications, the optical system includes a  
20   distal lens, positioned distal to the mirror, the distal lens having a rotational shape about  
the common rotation axis. For some applications, the optical system is configured to  
provide different levels of magnification for distal light arriving at the image sensor  
through the distal end of the optical system, and lateral light arriving at the image sensor  
through the curved distal portion of the lateral surface of the optical member.

- 25           For some applications, an outer surface of the piston head forming the pressure  
seal with the wall of the GI tract includes a low friction coating suitable for facilitating  
sliding of the piston head against the wall of the GI tract.

- 30           For some applications, the apparatus includes a fluid source, and at least one fluid  
supply tube coupled to the carrier, the tube in fluid communication with the fluid source,  
and the distal portion of the carrier is shaped so as to define one or more openings in fluid  
communication with the tube, the openings oriented so as to spray at least a portion of the  
optical member when fluid is provided by the fluid source.

For some applications, the apparatus includes an inflation element, fixed in a vicinity of the distal portion of the carrier, and adapted to increase a diameter of the carrier in the vicinity to an extent sufficient to position the optical member a distance from the wall sufficient to enable omnidirectional focusing of the optical system.

5        In an embodiment, the apparatus includes a vent tube, and the apparatus is adapted to facilitate the passage of the fluid out of the GI tract through the vent tube. For some applications, the vent tube is adapted to passively permit the passage of the fluid out of the GI tract. Alternatively, the vent tube is adapted to be coupled to a suction source, whereby to actively facilitate the passage of the fluid out of the GI tract.

10        In an embodiment, the piston head is adapted to be inflated so as to form and maintain the pressure seal with the wall of the GI tract. For some applications, the piston head is adapted to be intermittently deflated at least in part, while in the GI tract, whereby to facilitate the passage of the fluid out of the GI tract from the site within the GI tract distal to the piston head. For some applications, the piston head is shaped to define a  
15        proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

For some applications, the apparatus includes a piston-head-pressure sensor, adapted to sense a pressure within the piston head. For some applications, the piston-head-pressure sensor is adapted to be disposed within the piston head. Alternatively, the piston-head-pressure sensor is adapted to be disposed in a vicinity of the proximal  
20        opening of the GI tract. For some applications, the piston-head-pressure sensor is adapted to be disposed outside of the GI tract.

There is also provided, in accordance with an embodiment of the present invention, apparatus for use with a biologically-compatible-fluid pressure source, including:

25        an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

an inflatable piston head coupled to a distal portion of the carrier, the piston head shaped so as to define a proximal lobe and a distal lobe in fluid communication with each other, the piston head adapted to:

30        be inflated so as to form a pressure seal with a wall  
of the lumen after the carrier has been inserted into the  
lumen, and

be advanced distally through the body lumen in response to pressure from the fluid pressure source.

In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the carrier is adapted to be inserted through the proximal opening of the GI tract. In an embodiment, the GI tract includes a colon, and the carrier is adapted to be inserted through the proximal opening of the colon.

In an embodiment, the piston head is adapted to be in direct contact with the wall of the GI tract after the carrier has been inserted into the GI tract.

For some applications, a volume of a first one of the lobes is adapted to decrease in response to a constriction of the GI tract adjacent thereto, a volume of a second one of the lobes is adapted to remain constant in the absence of a change in GI tract diameter adjacent thereto, even if the volume of the first lobe is decreased, and a pressure within the first and second lobes is equal in steady state, regardless of the decrease in volume of the first lobe.

For some applications, the distal lobe has a diameter substantially equal to a diameter of the GI tract. For some applications, the distal lobe has a length of between 3 and 5 cm. For some applications, the piston head is shaped so as to define at least one lobe in addition to the first and second lobes.

For some applications, the piston head is shaped so as to define an intermediate portion at which the proximal and distal lobes articulate. For some applications, the intermediate portion has a diameter equal to between 10% and 40% of a diameter of the distal lobe.

In an embodiment, the apparatus includes a flexible vent tube, passing through the proximal and distal lobes of the piston head, and opening to a site within the GI tract distal to the piston head, and adapted to facilitate distal advancement of the piston head by facilitating passage of fluid from the site. For some applications, the apparatus includes a suction source, adapted to actively facilitate the passage of the fluid from the site.

For some applications, a volume of a first one of the lobes is adapted to decrease in response to a constriction of the GI tract adjacent thereto, a volume of a second one of the lobes is adapted to remain constant in the absence of a change in GI tract diameter

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adjacent thereto, even if the volume of the first lobe is decreased, and a pressure within the first and second lobes is equal in steady state, regardless of the decrease in volume of the first lobe.

For some applications, the distal lobe has a diameter substantially equal to a diameter of the GI tract. For some applications, the distal lobe has a length of between 3 and 5 cm. For some applications, the piston head is shaped so as to define at least one lobe in addition to the first and second lobes.

For some applications, the piston head is shaped so as to define an intermediate portion at which the proximal and distal lobes articulate. For some applications, the intermediate portion has a diameter equal to between 10% and 40% of a diameter of the distal lobe.

There is further provided, in accordance with an embodiment of the present invention, apparatus including:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen;

a balloon coupled to a distal portion of the carrier and adapted to be in direct contact with a wall of the lumen after the carrier has been inserted into the lumen; and a hydrophilic substance disposed at an external surface of the balloon.

In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the carrier is adapted to be inserted through the proximal opening of the GI tract. In an embodiment, the GI tract includes a colon, and the carrier is adapted to be inserted through the proximal opening of the colon.

For some applications, the balloon is shaped so as to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

There is still further provided, in accordance with an embodiment of the present invention, apparatus including:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

a balloon coupled to a distal portion of the carrier and adapted to be in direct contact with a wall of the lumen after the carrier has been inserted into the lumen, an

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outer surface of the balloon in contact with the wall of the lumen including a low friction coating suitable for facilitating sliding of the balloon against the wall of the lumen.

In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the carrier is adapted to be inserted through the proximal opening of the GI tract. In an embodiment, the GI tract includes a colon, and the carrier is adapted to be inserted through the proximal opening of the colon.

For some applications, the low friction coating includes a lubricant.

For some applications, the balloon is shaped so as to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

There is additionally provided, in accordance with an embodiment of the present invention, apparatus including:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

a balloon coupled to a distal portion of the carrier and adapted to be in direct contact with a wall of the lumen after the carrier has been inserted into the lumen, the balloon having a characteristic thickness of no more than 20 microns.

In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the carrier is adapted to be inserted through the proximal opening of the GI tract. In an embodiment, the GI tract includes a colon, and the carrier is adapted to be inserted through the proximal opening of the colon.

For some applications, the balloon has a characteristic thickness of no more than 10 microns. For some applications, an outer surface of the balloon in contact with the wall of the GI tract includes a low friction coating suitable for facilitating sliding of the balloon against the wall of the GI tract. For some applications, an outer surface of the balloon in contact with the wall of the GI tract includes a hydrophilic substance suitable for facilitating sliding of the balloon against the wall of the GI tract.

For some applications, the balloon is shaped so as to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

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There is yet additionally provided, in accordance with an embodiment of the present invention, apparatus for use with a biologically-compatible-fluid pressure source, including:

- an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and
- a piston head coupled to a distal portion of the carrier and adapted to:
  - form a pressure seal with a wall of the lumen after the carrier has been inserted into the lumen, and
  - be withdrawn proximally through the body lumen in response to pressure from the fluid pressure source.

In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the piston head is adapted to form the pressure seal with the wall of the GI tract after the carrier has been inserted into the GI tract. In an embodiment, the GI tract includes a colon, and the piston head is adapted to form the pressure seal with the wall of the colon after the carrier has been inserted into the colon.

In an embodiment, the piston head is adapted to be in direct contact with the wall of the GI tract after the carrier has been inserted into the GI tract.

For some applications, an outer surface of the piston head forming the pressure seal with the wall of the GI tract includes a low friction coating suitable for facilitating sliding of the piston head against the wall of the GI tract.

For some applications, the piston head is shaped so as to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

For some applications, the apparatus includes a pressure-application tube in fluid communication with (a) a distal site within the GI tract distal to the piston head, and (b) the fluid pressure source, the tube adapted to introduce the pressure to the distal site.

For some applications, the apparatus includes:

- a fluid source;
- an image-capturing device, coupled to the carrier in a vicinity of a distal end of the carrier; and
- at least one fluid supply tube coupled to the carrier, the tube in fluid communication with the fluid source,

and the distal end of the carrier is shaped so as to define one or more openings in fluid communication with the tube, the openings oriented so as to spray at least a portion of the image-capturing device when fluid is provided by the fluid source.

In an embodiment, the apparatus is adapted to facilitate passage of fluid out of the GI tract from a proximal site within the GI tract proximal to the piston head. For some applications, the apparatus includes a vent tube in fluid communication with the proximal site and outside the GI tract, the tube adapted to facilitate passage of fluid from the proximal site to the outside, so as to reduce a pressure at the proximal site. For some applications, the vent tube is adapted to passively permit the passage of the fluid from the proximal site. For some applications, the apparatus includes a suction source coupled to the vent tube, adapted to actively facilitate the passage of the fluid from the proximal site.

In an embodiment, the piston head is adapted to be inflated so as to form and maintain the pressure seal with the wall of the GI tract. For some applications, the apparatus includes a piston-head-pressure sensor, adapted to sense a pressure within the piston head. For some applications, the piston-head-pressure sensor is adapted to be disposed within the piston head. For some applications, the piston-head-pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract. For some applications, the piston-head-pressure sensor is adapted to be disposed outside of the GI tract.

For some applications, the apparatus includes a distal pressure sensor, adapted to sense a pressure within the GI tract distal to the piston head. For some applications, the distal pressure sensor is adapted to be disposed distal to the piston head. For some applications, the distal pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract. For some applications, the distal pressure sensor is adapted to be disposed outside of the GI tract.

For some applications, the apparatus includes a proximal pressure sensor, adapted to sense a pressure within the GI tract proximal to the piston head. For some applications, the proximal pressure sensor is adapted to be disposed in a vicinity of the piston head. For some applications, the proximal pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract. For some applications, the proximal pressure sensor is adapted to be disposed outside of the GI tract.



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For some applications, the apparatus includes a pressure sensor, adapted to measure a first pressure associated with operation of the apparatus; and a control unit, adapted to regulate a second pressure associated with operation of the apparatus responsive to the measurement of the pressure sensor. For some applications, the  
5 pressure sensor is adapted to measure a pressure selected from the list consisting of: a pressure distal to the piston head, a pressure proximal to the piston head, and a pressure within the piston head.

There is also provided, in accordance with an embodiment of the present invention, apparatus including:

10 an elongate carrier adapted to be inserted through a proximal opening of a body lumen;

an annular balloon, shaped so as to form an opening therethrough for insertion of the carrier, the balloon adapted to be at least partially inserted into the proximal opening, and to be expandable to form a pressure seal between the balloon and a wall of the body  
15 lumen in a vicinity of the proximal opening;

first and second fluid pressure sources;

a first tube, coupled between the first pressure source and an interior of the balloon; and

a second tube, coupled between the second pressure source and an interior of the  
20 lumen distal to the annular balloon.

In an embodiment, the body lumen includes a colon, the proximal opening includes a rectum, and the balloon is adapted to be at least partially inserted into the rectum, and to be expandable to form the pressure seal between the balloon and the wall of the colon.

25 For some applications, at least one of the first and second pressure sources is adapted to be positioned outside the colon.

For some applications, the apparatus includes a ring coupled to the balloon, the ring adapted to abut against the rectum, and the ring shaped so as to form an opening therethrough for insertion of the carrier.

30 For some applications, the first pressure source includes a powered fluid pressure source. Alternatively, the first pressure source includes a manually-operated fluid

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pressure source. For some applications, the manually-operated pressure source includes a syringe.

There is further provided, in accordance with an embodiment of the present invention, apparatus including:

5       an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

          an inflatable cuff, shaped so as to define an opening therethrough through which the carrier can be inserted, the cuff adapted to form a pressure seal with a wall of the body lumen when the cuff is in an inflated state in a vicinity of the proximal opening.

10       In an embodiment, the body lumen includes a colon, the proximal opening includes a rectum, and the carrier is adapted to be inserted through the rectum of the colon.

There is still further provided, in accordance with an embodiment of the present invention, apparatus for use with a fluid source, the apparatus including:

15       an elongate carrier, adapted to be inserted through a proximal opening of a body lumen;

          an image-capturing device, fixed to the carrier in a vicinity of a distal end of the carrier; and

20       at least one fluid supply tube coupled to the carrier, the tube in fluid communication with the fluid source,

          wherein the distal end of the carrier is shaped so as to define one or more openings in fluid communication with the tube, the openings oriented so as to spray at least a portion of the image-capturing device when fluid is provided by the fluid source.

25       In an embodiment, the body lumen includes a colon, and the carrier is adapted to be inserted through the proximal opening of the colon.

30       For some applications, the distal end of the carrier is shaped so as to define between 4 and 10 openings through which the fluid flows when provided by the fluid source. For some applications, the openings are disposed circumferentially about the distal end of the carrier. For some applications, the openings are positioned at a circumferential angle, so as to create a vortex around the image-capturing device when the fluid is provided by the fluid source.

For some applications, the image-capturing device includes an optical member that is shaped so as to define a lateral surface configured to provide omnidirectional lateral viewing, and the openings are oriented so as to spray at least a portion of the lateral surface of the optical member. For some applications, the optical member is shaped so as to define a forward surface configured to provide forward viewing, and the openings are oriented so as to spray at least a portion of the forward surface of the optical member.

There is additionally provided, in accordance with an embodiment of the present invention, apparatus for use in a body lumen having a proximal opening, the apparatus including:

an elongate carrier, adapted to be inserted through the proximal opening of the lumen;

an image-capturing device, fixed in a first vicinity of a distal end of the carrier, and adapted to provide omnidirectional lateral viewing; and

an inflation element, fixed in a second vicinity of the distal end, and adapted to increase a diameter of the carrier in the second vicinity to an extent sufficient to position the image-capturing device a distance from a wall of the lumen sufficient to enable omnidirectional focusing of the image-capturing device.

In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the carrier is adapted to be inserted through the proximal opening of the GI tract.

For some applications, the inflation element is adapted to increase the diameter of the carrier in the second vicinity such that the image-capturing device is at least 15 mm from the wall.

For some applications, the inflation element includes an expandable sponge. Alternatively or additionally, the inflation element includes a set of one or more rings, selected from the list consisting of: inflatable rings, and expandable rings. Further alternatively or additionally, the inflation element includes an inflatable balloon.

In an embodiment, the GI tract includes a colon, and the carrier is adapted to be inserted through the proximal opening of the colon. For some applications, the inflation element is adapted to increase the diameter of the carrier in the second vicinity to between 30 and 45 mm.

There is yet additionally provided, in accordance with an embodiment of the present invention, apparatus for use in a body lumen having a proximal opening, the apparatus including:

first and second fluid pressure sources;

5 an elongate carrier, adapted to be inserted through the proximal opening of the body lumen;

an inflatable piston head coupled to a distal portion of the carrier, and adapted to form a pressure seal with a wall of the lumen after the carrier has been inserted into the lumen;

10 a first passageway in fluid communication with the first pressure source and a proximal portion of the lumen proximal to the piston head;

a second passageway in fluid communication with the second pressure source and the piston head;

15 first and second pressure sensors, adapted to measure a first measurable pressure in the proximal portion of the lumen, and a second measurable pressure in the piston head, respectively; and

a control unit, adapted to cause the piston head to be advanced distally in the lumen by:

20 while the first pressure source applies a first applied pressure to the proximal portion of the lumen,

regulating the second measurable pressure in the piston head to be equal to the first measurable pressure in the proximal portion of the lumen plus a positive value, by driving the second pressure source to apply a second applied pressure.

25 In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the carrier is adapted to be inserted through the proximal opening of the GI tract. In an embodiment, the GI tract includes a colon, and the carrier is adapted to be inserted through the proximal opening of the colon.

In an embodiment, the piston is adapted to be in direct contact with the wall of the GI tract after the carrier has been inserted into the GI tract.

30 For some applications, the apparatus includes a third passageway in fluid communication with a portion of the GI tract distal to the piston head and a site outside the GI tract.

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For some applications, the first passageway has a diameter of between 3 and 6 mm.

For some applications, the first pressure sensor is adapted to be disposed in a vicinity of the piston head. Alternatively, for some applications, the first pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract. For some applications, the first pressure sensor is adapted to be disposed outside of the GI tract.

For some applications, the second pressure sensor is adapted to be disposed within the piston head. For some applications, the second pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract. For some applications, the second pressure sensor is adapted to be disposed outside of the GI tract.

For some applications, the positive value is between 1 and 5 millibar. For some applications, the positive value is between 1.5 and 2.5 millibar.

For some applications, the control unit is adapted to set the second measurable pressure in the piston head at an initial value prior to application of the first applied pressure, by driving the second pressure source to apply the second applied pressure. For some applications, the initial value is between 5 and 15 millibar, and the control unit is adapted to set the second measurable pressure at between 5 and 15 millibar. For some applications, the control unit is adapted to regulate the second measurable pressure to be equal to the greater of: (a) the initial value, and (b) the first measurable pressure plus the positive value.

There is also provided, in accordance with an embodiment of the present invention, apparatus for use with a biologically-compatible-fluid pressure source, including:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

a distal piston head coupled to a distal portion of the carrier and adapted to:

form a pressure seal with a wall of the lumen after the carrier has been inserted into the lumen, and

be advanced distally through the body lumen in response to pressure from the fluid pressure source applied to an external surface of the distal piston head.

In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the distal piston head is adapted to form the pressure seal with the wall of the GI tract after the carrier has been inserted into the GI tract. In an embodiment, the GI tract includes a colon, and the distal piston head is adapted to form the pressure seal with the wall of the colon after the carrier has been inserted into the colon.

In an embodiment, the distal piston head is adapted to be in direct contact with the wall of the GI tract after the carrier has been inserted into the GI tract.

For some applications, an outer surface of the distal piston head forming the pressure seal with the wall of the GI tract includes a low friction coating suitable for facilitating sliding of the distal piston head against the wall of the GI tract.

For some applications, the apparatus includes:

a fluid source;

an optical member coupled in a vicinity of the distal portion of the carrier; and

at least one fluid supply tube coupled to the carrier, the tube in fluid communication with the fluid source,

and the distal portion of the carrier is shaped so as to define one or more openings in fluid communication with the tube, the openings oriented so as to spray at least a portion of the optical member when fluid is provided by the fluid source.

For some applications, the apparatus includes:

an optical system including an optical member configured to provide omnidirectional lateral viewing; and

an inflation element, fixed in a vicinity of the distal portion of the carrier, and adapted to increase a diameter of the carrier in the vicinity to an extent sufficient to position the optical member a distance from the wall sufficient to enable omnidirectional focusing of the optical system.

In an embodiment, the apparatus is adapted to facilitate distal advancement of the distal piston head by facilitating passage of fluid out of the GI tract from a distal site within the GI tract distal to the distal piston head. For some applications, the apparatus is adapted to facilitate the passage of an amount of the fluid out of the GI tract from the distal site sufficient to maintain a pressure of less than 10 millibar at the distal site. For some applications, the apparatus is adapted to facilitate the passage of at least 100 cc of the fluid out of the GI tract from the distal site, per minute that the distal piston head

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advances distally. For some applications, the apparatus is adapted to facilitate the passage of at least 300 cc of the fluid out of the GI tract from the distal site, per minute that the distal piston head advances distally.

For some applications, the apparatus is adapted to facilitate the passage of at least  
5 3 cc of the fluid out of the GI tract from the distal site, per centimeter that the distal piston head advances distally. For some applications, the apparatus is adapted to facilitate the passage of at least 10 cc of the fluid out of the GI tract from the distal site, per centimeter that the distal piston head advances distally.

For some applications, the apparatus includes a vent tube, and the apparatus is  
10 adapted to facilitate the passage of the fluid out of the GI tract from the distal site within the GI tract through the vent tube. For some applications, the vent tube is shaped to define an inner diameter thereof that is between 1 and 3 millimeters. For some applications, the vent tube is adapted to passively permit the passage of the fluid out of the GI tract from the distal site within the GI tract.

For some applications, the vent tube is adapted to be coupled to a suction source,  
15 whereby to actively facilitate the passage of the fluid out of the GI tract from the distal site within the GI tract. For some applications, the vent tube is adapted to be coupled to the suction source such that during operation of the apparatus, a pressure distal to the distal piston head is between -5 millibar and +15 millibar.

For some applications, the apparatus includes a suction source coupled to the vent  
20 tube, adapted to actively facilitate the passage of the fluid out of the GI tract from the distal site within the GI tract. For some applications, the suction source is adapted to maintain a pressure distal to the distal piston head is between -5 millibar and +15 millibar.

For some applications, the distal piston head is adapted to be inflated so as to form  
25 and maintain the pressure seal with the wall of the GI tract, and the distal piston head is adapted to be intermittently deflated at least in part, while in the GI tract, whereby to facilitate the passage of the fluid out of the GI tract from the site within the GI tract distal to the distal piston head.

In an embodiment, the distal piston head is adapted to be inflated so as to form  
30 and maintain the pressure seal with the wall of the GI tract. For some applications, the apparatus includes an auxiliary piston head, coupled to the carrier at a position proximal

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to the distal piston head; the auxiliary piston head is adapted to be inflated so as to form and maintain an auxiliary pressure seal with the wall of the GI tract; and (a) at at least one time while the carrier is within the GI tract, the distal piston head is adapted to be in a state of being already deflated at least in part, simultaneously with the auxiliary piston head being already inflated and being advanced distally through the GI tract in response to pressure from the fluid pressure source, and (b) at at least one other time while the carrier is within the GI tract, the auxiliary piston head is adapted to be in a state of being already deflated at least in part, simultaneously with the distal piston head being already inflated and being advanced distally through the GI tract in response to pressure from the fluid pressure source.

For some applications, the apparatus includes a piston-head-pressure sensor, adapted to sense a pressure within the distal piston head. For some applications, the piston-head-pressure sensor is adapted to be disposed within the distal piston head. For some applications, the piston-head-pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract. For some applications, the piston-head-pressure sensor is adapted to be disposed outside of the GI tract. For some applications, the apparatus includes a distal pressure sensor, adapted to sense a pressure within the GI tract distal to the distal piston head. For some applications, the distal pressure sensor is adapted to be disposed distal to the distal piston head. Alternatively, for some applications, the distal pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract. For some applications, the distal pressure sensor is adapted to be disposed outside of the GI tract.

For some applications, the apparatus includes a proximal pressure sensor, adapted to sense a first measurable pressure, within a proximal portion of the GI tract proximal to the distal piston head. For some applications, the apparatus includes a distal pressure sensor, adapted to sense a pressure distal to the distal piston head. For some applications, the proximal pressure sensor is adapted to be disposed in a vicinity of the distal piston head.

For some applications, the proximal pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract. For some applications, the proximal pressure sensor is adapted to be disposed outside of the GI tract. For some applications, the apparatus includes a piston-head-pressure sensor, adapted to sense a second



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measurable pressure, within the distal piston head. For some applications, the pressure source includes a first pressure source, adapted to apply a first applied pressure to the proximal portion of the GI tract, and the apparatus includes:

5 a second pressure source, adapted to apply a second applied pressure to an interior of the distal piston head; and

a control unit, adapted to advance the distal piston head distally in the GI tract by:

while the first pressure source applies the first applied pressure to the proximal portion,

10 regulating the second measurable pressure in the distal piston head to be equal to the first measurable pressure in the proximal portion of the GI tract plus a positive value, by driving the second pressure source to apply the second applied pressure.

For some applications, the apparatus includes a pressure sensor, adapted to measure a first pressure associated with operation of the apparatus; and a control unit,  
15 adapted to regulate a second pressure associated with operation of the apparatus responsive to the measurement of the pressure sensor. For some applications, the pressure sensor is adapted to measure a pressure selected from the list consisting of: a pressure distal to the distal piston head, a pressure proximal to the distal piston head, and a pressure within the distal piston head. For some applications, the control unit is adapted  
20 to regulate the pressure being measured by the pressure sensor. For some applications, the control unit is adapted to regulate a pressure other than that being measured by the pressure sensor.

For some applications, the distal piston head is shaped to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

25 For some applications, a volume of a first one of the lobes is adapted to decrease in response to a constriction of the GI tract adjacent thereto, a volume of a second one of the lobes is adapted to remain constant in the absence of a change in GI tract diameter adjacent thereto, even if the volume of the first lobe is decreased, and a pressure within the first and second lobes is equal in steady state, regardless of the decrease in volume of  
30 the first lobe.

For some applications, the distal piston head is adapted to be at an inflation pressure between 10 and 60 millibar during advancement through the GI tract. For some

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applications, the distal piston head is adapted to advance through the GI tract in response to a pressure from the fluid pressure source that is between 30% and 100% of the inflation pressure. For some applications, the distal piston head is adapted to advance through the GI tract in response to a pressure from the fluid pressure source that is between 50% and  
5 100% of the inflation pressure.

For some applications, the distal piston head is adapted to be at an inflation pressure between 20 and 50 millibar during advancement through the GI tract. For some applications, the distal piston head is adapted to be at an inflation pressure between 30 and 45 millibar during advancement through the GI tract. For some applications, the  
10 distal piston head is adapted to advance through the GI tract in response to a pressure from the fluid pressure source that is between 30% and 100% of the inflation pressure. For some applications, the distal piston head is adapted to advance through the GI tract in response to a pressure from the fluid pressure source that is between 50% and 100% of the inflation pressure. For some applications, the distal piston head is adapted to advance  
15 through the GI tract in response to a pressure from the fluid pressure source that is between 50% and 80% of the inflation pressure.

For some applications, the distal piston head is shaped to define a distally-narrowing portion, and is adapted to be inserted into the GI tract such that a tip of the distally-narrowing portion points in a distal direction when the distal piston head is in the  
20 GI tract. For some applications, a proximal base of the distally-narrowing portion has a characteristic fully-inflated diameter that is larger than a diameter of at least a part of the GI tract through which the distally-narrowing portion is adapted to pass, whereby the base of the distally-narrowing portion does not inflate fully when the base is in that part of the GI tract.

25 There is further provided, in accordance with an embodiment of the present invention, apparatus for use in a body lumen having a proximal opening, the apparatus including:

- an elongate carrier, adapted to be inserted through the proximal opening of the body lumen;
- 30 an inflatable piston head coupled to a distal portion of the carrier, and adapted to form a pressure seal with a wall of the lumen after the carrier has been inserted into the lumen; and

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a biologically-compatible fluid proximal pressure source, adapted to be in fluid communication with a proximal portion of the lumen proximal to the piston head, and to apply pressure sufficient to advance the carrier distally through the body lumen.

In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the piston head is adapted to form the pressure seal with the wall of the GI tract. In an embodiment, the GI tract includes a colon, and the piston head is adapted to form the pressure seal with the wall of the colon.

In an embodiment, the piston head is adapted to be in direct contact with the wall of the GI tract.

For some applications, the apparatus includes a first passageway, and the proximal pressure source is in the fluid communication with the proximal portion of the GI tract via the first passageway.

For some applications, the apparatus includes a piston pressure source, adapted to be in fluid communication with the piston head, and to apply pressure to the piston head in order to inflate the piston head.

For some applications, the apparatus includes a second passageway, and the piston pressure source is in the fluid communication with the piston head via the second passageway.

For some applications, the apparatus includes a proximal pressure sensor, adapted to measure a pressure in the proximal portion of the GI tract; and a piston pressure sensor, adapted to measure a pressure in the piston head.

For some applications, the apparatus includes a proximal pressure sensor, adapted to measure a pressure in the proximal portion of the GI tract. For some applications, the proximal pressure sensor is adapted to be disposed in a vicinity of the piston head. Alternatively, for some applications, the proximal pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract. For some applications, the proximal pressure sensor is adapted to be disposed outside of the GI tract.

For some applications, the apparatus includes a piston pressure sensor, adapted to measure a pressure in the piston head. For some applications, the piston pressure sensor is adapted to be disposed within the piston head. For some applications, the piston pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI

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tract. For some applications, the piston pressure sensor is adapted to be disposed outside of the GI tract.

For some applications, the apparatus includes a vent tube, adapted to be in fluid communication with a distal portion of the GI tract distal to the piston head, and with  
5 outside of the GI tract, and to facilitate distal advancement of the piston head by facilitating passage of fluid out of the GI tract from the distal portion. For some applications, the apparatus includes a distal pressure sensor, adapted to measure a pressure in the distal portion of the GI tract. For some applications, the distal pressure sensor is adapted to be disposed distal to the piston head. For some applications, the  
10 distal pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract. For some applications, the distal pressure sensor is adapted to be disposed outside of the GI tract.

For some applications, the apparatus is adapted to facilitate the passage of an amount of the fluid out of the GI tract from the distal portion sufficient to maintain a  
15 pressure of less than 10 millibar at the distal portion.

For some applications, the vent tube is adapted to passively permit the passage of the fluid out of the GI tract from the distal portion.

For some applications, the apparatus includes a suction source coupled to the vent tube, adapted to actively facilitate the passage of the fluid out of the GI tract from the  
20 distal portion.

For some applications, the apparatus is adapted to facilitate the passage of at least 100 cc of the fluid out of the GI tract from the distal portion, per minute that the piston head advances distally. For some applications, the apparatus is adapted to facilitate the passage of at least 300 cc of the fluid out of the GI tract from the distal portion, per  
25 minute that the piston head advances distally.

For some applications, the apparatus is adapted to facilitate the passage of at least 3 cc of the fluid out of the GI tract from the distal portion, per centimeter that the piston head advances distally. For some applications, the apparatus is adapted to facilitate the passage of at least 10 cc of the fluid out of the GI tract from the distal portion, per  
30 centimeter that the piston head advances distally.

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There is still further provided, in accordance with an embodiment of the present invention, apparatus for use in a body lumen having a proximal opening, the apparatus including:

5 an elongate carrier, adapted to be inserted through the proximal opening of the body lumen;

an inflatable piston head coupled to a distal portion of the carrier, and adapted to form a pressure seal with a wall of the lumen after the carrier has been inserted into the lumen;

10 a biologically-compatible fluid proximal pressure source, adapted to be in fluid communication with a proximal portion of the lumen proximal to the piston head, and to apply pressure sufficient to advance the carrier distally through the body lumen; and

a piston head pressure sensor, adapted to sense a piston head pressure in the piston head, the piston head pressure sensor disposed in a vicinity of the proximal opening of the lumen, and in fluid communication with an interior of the piston head.

15 In an embodiment, the lumen includes a gastrointestinal (GI) tract, and the piston head is adapted to form the pressure seal with the wall of the GI tract. In an embodiment, the GI tract includes a colon, and the piston head is adapted to form the pressure seal with the wall of the colon.

20 In an embodiment, the piston head is adapted to be in direct contact with the wall of the GI tract.

For some applications, the piston head pressure sensor is adapted to be in fluid communication with the interior of the piston head via a passageway, a proximal end of which is disposed in the vicinity of the proximal opening of the GI tract.

25 For some applications, the piston head pressure sensor is adapted to be disposed outside of the GI tract.

For some applications, the apparatus includes a biologically-compatible fluid piston head pressure source, adapted to be in fluid communication with the interior of the piston head via a passageway, and the piston head pressure sensor is adapted to be in fluid communication with the interior of the piston head via the passageway.

30 For some applications, the apparatus includes a proximal portion pressure sensor, adapted to sense a proximal portion pressure in the proximal portion of the GI tract, and

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disposed in a vicinity of the proximal opening of the GI tract. For some applications, the proximal portion pressure sensor is adapted to be disposed outside of the GI tract.

For some applications, the apparatus includes a distal portion pressure sensor, adapted to sense a distal portion pressure in a distal portion of the GI tract distal to the piston head, and disposed in a vicinity of the proximal opening of the GI tract. For some applications, the distal portion pressure sensor is adapted to be disposed outside of the GI tract.

There is additionally provided, in accordance with an embodiment of the present invention, a method including:

- 10 forming a pressure seal between a piston head and a wall of a body lumen;  
advancing the piston head distally through the body lumen by:
  - applying fluid pressure to an external surface of the piston head, and
  - facilitating passage of fluid out of the lumen from a site
- 15 within the lumen distal to the piston head; and  
providing omnidirectional lateral viewing from a vicinity of the piston head.

There is yet additionally provided, in accordance with an embodiment of the present invention, a method including:

- forming a pressure seal between a wall of a body lumen and a piston head shaped
- 20 so as to define a proximal lobe and a distal lobe in fluid communication with each other;  
and
- advancing the piston head distally through the body lumen by applying fluid pressure to an external surface of the piston head.

There is also provided, in accordance with an embodiment of the present invention, a method including:

- 25 providing an elongate carrier having a balloon coupled to a distal portion thereof, the balloon having a hydrophilic substance disposed at an external surface thereof; and
- inserting the elongate carrier through a proximal opening of a body lumen, such that the balloon comes in direct contact with a wall of the lumen.

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There is further provided, in accordance with an embodiment of the present invention, a method including:

providing an elongate carrier having a balloon coupled to a distal portion thereof, an outer surface of the balloon having a low friction coating suitable for facilitating  
5 sliding of the balloon against the wall of the lumen; and

inserting the elongate carrier through a proximal opening of a body lumen, such that the outer surface of the balloon comes in direct contact with a wall of the lumen.

There is still further provided, in accordance with an embodiment of the present invention, a method including:

10 providing an elongate carrier having a balloon coupled to a distal portion thereof, the balloon having a characteristic thickness of no more than 20 microns; and

inserting the elongate carrier through a proximal opening of a body lumen, such that the balloon comes in direct contact with a wall of the lumen.

There is additionally provided, in accordance with an embodiment of the present  
15 invention, a method including:

forming a pressure seal between a piston head and a wall of a body lumen; and  
applying fluid pressure to an external surface of the piston head to withdraw the piston head proximally through the body lumen.

There is yet additionally provided, in accordance with an embodiment of the  
20 present invention, a method including:

inserting an annular balloon at least partially into a proximal opening of a body lumen;

expanding the balloon to form a seal between the balloon and a wall of the body lumen in a vicinity of the proximal opening;

25 inserting an elongate carrier into the lumen through an opening that passes through the balloon; and

applying pressure to an interior of the lumen distal to the balloon.

There is also provided, in accordance with an embodiment of the present invention, a method including:

30 inserting an inflatable cuff at least partially into a proximal opening of a body lumen;

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inflating the cuff to form a seal with a wall of the body lumen in a vicinity of the proximal opening; and

inserting an elongate carrier into the lumen through an opening that passes through the cuff.

5        There is further provided, in accordance with an embodiment of the present invention, a method including:

inserting, through a proximal opening of a body lumen, an elongate carrier having an image-capturing device fixed thereto in a vicinity of a distal end thereof; and

10        spraying, from one or more openings in the distal end of the carrier, fluid onto at least a portion of the image-capturing device.

There is still further provided, in accordance with an embodiment of the present invention, a method including:

15        inserting, through a proximal opening of a body lumen, an elongate carrier having an image-capturing device fixed thereto in a first vicinity of a distal end of the carrier, for providing omnidirectional lateral viewing; and

increasing a diameter of the carrier in a second vicinity of the distal end to an extent sufficient to position the image-capturing device a distance from a wall of the lumen sufficient to enable omnidirectional focusing of the image-capturing device.

20        There is additionally provided, in accordance with an embodiment of the present invention, a method including:

forming a pressure seal between an inflatable piston head and a wall of a body lumen;

measuring a first measurable pressure in a proximal portion of the lumen proximal to the piston head, and a second measurable pressure in the piston head; and

25        advancing the piston head distally through the lumen by:

applying a first applied pressure to the proximal portion of the lumen, and

30        regulating the second measurable pressure in the piston head to be equal to the first measurable pressure in the proximal portion of the lumen plus a positive value, by applying a second applied pressure to piston head.



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There is yet additionally provided, in accordance with an embodiment of the present invention, a method including:

forming a pressure seal between a distal piston head and a wall of a body lumen;  
and

- 5       applying fluid pressure to an external surface of the distal piston head to advance the piston head distally through the lumen.

There is also provided, in accordance with an embodiment of the present invention, a method including:

- forming a pressure seal between a piston head and a wall of a body lumen;  
10       applying fluid pressure to an external surface of the distal piston head to advance the piston head distally through the lumen; and  
sensing, at a vicinity of a proximal opening of the lumen, a piston head pressure in the piston head.

## BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Fig. 1 is a simplified pictorial illustration of a system, constructed and operative in accordance with an embodiment of the present invention, which may be suitable for imaging body lumens, such as the GI tract;

Figs. 2 and 3 are simplified sectional illustrations of distal and proximal portions, respectively, of the system of Fig. 1;

Fig. 4 is a simplified sectional illustration of a carrier of the system of Fig. 1, the section being taken transverse to a longitudinal axis of the carrier, in accordance with an embodiment of the present invention;

Figs. 5A, 5B and 5C are simplified pictorial illustrations of the system of Fig. 1, showing three steps of a mode of operation thereof, wherein inflatable piston heads are inflated and deflated to negotiate obstacles in a body lumen, in accordance with an embodiment of the present invention;

Fig. 6 is a pictorial illustration of a system for use in a body lumen, constructed and operative in accordance with an embodiment of the present invention;

Fig. 7 is a pictorial illustration of an inflated conical balloon, which is adapted for use in accordance with an embodiment of the present invention;

Fig. 8 is a pictorial illustration of a partially-inflated conical balloon in a body lumen, in accordance with an embodiment of the present invention;

Fig. 9A is a pictorial illustration of the cross-section of a fully inflated portion of a conical balloon, in accordance with an embodiment of the present invention;

Fig. 9B is a pictorial illustration of the cross-section of a partially inflated portion of a conical balloon, in accordance with an embodiment of the present invention;

Figs. 10A and 10B are pictorial illustrations of a system for use in a body lumen, constructed and operative in accordance with an embodiment of the present invention;

Figs. 11A and 11B are pictorial illustrations of the multi-lobed piston head of Figs. 10A and 10B, in accordance with an embodiment of the present invention;

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Fig. 12 is a schematic cross-sectional illustration of an optical system, in accordance with an embodiment of the present invention;

Figs. 13A and 13B are pictorial illustrations of another system for use in a body lumen, in accordance with an embodiment of the present invention;

5      Fig. 14 is a schematic illustration of an inserter, in accordance with an embodiment of the present invention; and

Fig. 15 is a schematic illustration of a cleaning system, in accordance with an embodiment of the present invention.

### DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Figs. 1-3, which illustrate a system 10, constructed and operative in accordance with an embodiment of the present invention.

As seen best in Fig. 3, system 10 may include a guide member 12, which may be constructed of any medically safe material, such as but not limited to, plastic or metal. Guide member 12 may be formed with a first passageway 14 connected to a source 16 of a pressurized biologically-compatible fluid ("fluid pressure source 16"), such as but not limited to, a source of pressurized air, CO<sub>2</sub> or water. Guide member 12 may be at least partially insertable into a proximal opening 18 (e.g., the rectum) of a body lumen 20 (e.g., the colon). Guide member 12 may include an annular ring 22 for abutting against the proximal opening 18.

Guide member 12 may be formed with a bore 24 through which an elongate carrier 26 may be arranged for sliding movement. An O-ring 28 may be provided for dynamically sealing carrier 26 in its sliding motion relative to the guide member 12. Carrier 26 may be any slender wire, catheter or tube and the like, constructed of any medically safe material, such as but not limited to, a flexible plastic or metal. Carrier 26, including its tip, may be safely deflected and steered through body lumen 20.

In an embodiment of the present invention, guide member 12 comprises a microcuff, which forms a seal with the wall of lumen 20, in order to maintain positive pressure within lumen 20. For example, the microcuff may comprise a cuff manufactured by Microcuff GmbH (Weinheim, Germany), and/or described in the above-mentioned PCT Publication WO 04/069057, US Patent Application Publication 2003/0000526, and/or PCT Publication WO 03/045487. The creation of such positive pressure is described hereinbelow.

A piston head 30 may be mounted on carrier 26. Piston head 30 may be inflatable, and as such may be constructed of any medically safe elastomeric material, such as but not limited to, a bladder or membrane made of polyurethane or silicone rubber, for example. An image-capturing device 32 may be mounted on carrier 26 distal to piston head 30. Piston head 30 is typically fixed to carrier 26 and sealed thereto with O-rings 33, but optionally may be arranged to slide on carrier 26 up to some distal stop which arrests further distal motion of piston head 30 (image-capturing device 32 may

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serve as the distal stop, for example). Image-capturing device 32 may comprise, without limitation, a camera (e.g., CCD or CMOS), or alternatively x-ray, ultrasonic, MRI, infrared and/or microwave imaging devices.

5 Other therapeutic or diagnostic devices may be mounted on or in carrier 26, such as but not limited to, a magnet, drug delivery devices (e.g., via iontophoresis), gene therapy devices and others.

Carrier 26 may include a second passageway 34 in fluid communication with piston head 30, connected to a source of fluid pressure 36 (e.g., pressurized air or water) for inflating piston head 30. For some applications, piston head-inflation fluid pressure  
10 source 36 is regulated to maintain a generally constant pressure within piston head 30, regardless of changes of volume of the piston head which occur in response to diameter changes of lumen 20.

A vent tube 38 may pass through or around piston head 30, having an opening 40 distal to piston head 30 through which fluid is ventable to the outside. That is, the  
15 proximal end of vent tube 38 vents the fluid past guide member 12 to the outside. For some applications, the proximal end of vent tube 38 may be connected to a suction source (not shown) for sucking fluid through vent tube 38. "Fluid," as used herein, including in the claims, includes liquids and gases.

In an embodiment, vent tube 38 is not used, but instead piston head 30 is  
20 temporarily deflated (at least in part), intermittently and/or in response to excess pressure accumulating distal to piston head 30. The temporary deflation of the piston head allows venting of the distal pressure to occur through passageway 14, typically in conjunction with a temporary decoupling of passageway 14 from fluid pressure source 16.

A power supply tube 42 (e.g., containing electrical wires, fiber optics, etc.) may  
25 pass through carrier 26, for connection to image-capturing device 32. Alternatively, the electrical and optical components of image-capturing device 32 may have their own internal power source, with no need for external wiring. Image-capturing device 32 may wirelessly transmit or receive data to or from an external processor (not shown). The components of system 10 may be fully automated with sensors and operate in a closed or  
30 open control loop.

A fluid supply tube 44 may pass through carrier 26, which may be connected to a fluid source (not shown), e.g., pressurized water, for cleaning the area near image-capturing device 32, or in combination with the vent tube 38, for cleaning body lumen 20 itself (e.g., the colon).

5 Experiments carried out by the inventors have shown that the system, as described hereinabove, is able to safely and efficiently advance a colonoscope or other tool through the colon of an anesthetized 90 kg pig. In these experiments, elongate carrier 26 was generally radio-opaque, and its motion was tracked in real-time using fluoroscopic imaging. Vent tube 38 was utilized, having an inner diameter of 2 mm. It acted passively  
10 (without being connected to a suction source), in order to allow pressure accumulating distal to piston head 30 to be vented to the outside.

In these experiments, a range of operating pressures were examined. The proximal pressure and the pressure within the piston head (intra-head pressure) were controlled, and values were recorded at which satisfactory movement of piston head 30  
15 was observed. In general, for intra-head pressures ranging between 25 and 40 millibar, movement of piston head 30 was observed when the proximal pressure reached 30-100% of the intra-head pressure.

Typically, when the proximal pressure was below a threshold value, no movement was observed. As the proximal pressure was elevated above the threshold value, piston  
20 head 30 advanced through the colon. If the proximal pressure increased significantly above the threshold pressure (e.g., 2-10 millibar above the threshold pressure), then there was pressure leakage between piston head 30 and the wall of lumen 20, and advancement of piston head 30 ceased. In response to such a leak, the proximal pressure was lowered, vent tube 38 allowed the excess accumulated distal pressure to vent to the outside, and  
25 movement of piston head 30 recommenced.

In an experiment, an inflatable piston head was formed of thin silicone, and was shaped to have a distal lobe, a proximal lobe, and an intermediate portion connecting the distal and proximal lobes. (See Figs. 10A and 10B.) For an intra-head pressure of 30  
30 millibar, the piston head advanced through the colon when the proximal pressure was maintained between 10 and 20 millibar. During advancement of the piston head, vent tube 38 vented to the outside the pressure that accumulated due to the advancement of the piston head. Leakage around the piston head was observed for proximal pressures greater

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than about 20 millibar. For an intra-head pressure of 40 millibar, the piston head advanced through the colon when the proximal pressure was maintained between 27 and 30 millibar, both on straight and curved portions of the colon. For straight portions of the colon, proximal pressures of as low as 20 millibar were also sufficient to produce  
5 satisfactory movement of the piston head.

Although the rate of advance of the two-lobed piston head was found to vary with the selected pressures, in one experiment using a thin-walled two-lobed piston head, a total time of 2 minutes passed during the advancing of a colonoscope 1.5 meters into the colon of the pig. In another experiment, using a thick-walled two-lobed piston head, an  
10 intra-head pressure of 70 millibar and proximal pressure of 50 millibar resulted in 1.5 meters of colonoscope advancement in 1 minute 41 seconds. Thin-walled piston heads useful for these embodiments of the invention typically have a head wall thickness between 10 and 100 microns, e.g., 50 microns or less than 20 microns, or a head wall thickness of less than 10 microns. Thick-walled piston heads useful for these  
15 embodiments of the invention typically have a head wall thickness greater than 100 microns, e.g., 150 microns, or 250 microns.

In another experiment, the piston head was formed of polyurethane, and was shaped like a cone, as described hereinbelow with reference to Figs. 7-9. In this experiment, satisfactory advancement of the piston head was obtained at a proximal  
20 pressure of 35 millibar, when the intra-head pressure was also 35 millibar. The satisfactory advancement was obtained both on straight and curved portions of the colon.

It is noted that in these experiments, during the time when the intra-head pressure was kept constant, the volume of the piston head changed actively in response to changes in diameter of lumen 20.

25 Reference is now made to Figs. 1, 2 and 5A-C, which illustrate operation of system 10, in accordance with an embodiment of the present invention. In this embodiment, an auxiliary piston head 46 may be mounted on the carrier proximal to distal piston head 30. Auxiliary piston head 46, which like piston head 30 may be inflatable, may be fixed axially to carrier 26 at a fixed distance from piston head 30.  
30 Auxiliary piston head 46 may be sealed with respect to carrier 26 with O-rings 47. Carrier 26 may include a third passageway 48 in fluid communication with auxiliary

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piston head 46, connected to a source of fluid pressure 50 for inflating auxiliary piston head 46.

System 10 may be inserted in the rectum with piston heads 30 and 46 initially deflated to facilitate insertion. Distal piston head 30 may then be gently inflated until it expands to the inner wall of body lumen 20. This configuration is shown in Fig. 1. Pressurized fluid (e.g., air) from fluid pressure source 16 may be introduced into the colon through the first passageway 14 of guide member 12. The pressurized fluid creates greater fluid pressure acting on the proximal side of piston head 30 than on the distal side of piston head 30. Opening 40 of vent tube 38 may assist in creating the pressure difference across piston head 30, either passively, or actively via applied suction. This pressure difference propels piston head 30 together with carrier 26 distally into the body lumen (in this example, the colon), as indicated by arrow 60. Image-capturing device 32 may capture images of body lumen 20 as system 10 travels therethrough.

In an embodiment of the present invention, the techniques described herein for propulsion by creating a pressure difference are applied in a reverse manner to actively propel piston head 30 together with carrier 26 proximally, i.e., to withdraw system 10 from lumen 20. Pressurized fluid (e.g., air) from a fluid pressure source is introduced to the distal side of piston head 30, via a pressure-application tube passing through or around piston head 30. Optionally, vent tube 38 serves as the pressure-application tube during withdrawal. The pressurized fluid creates greater fluid pressure acting on the distal side of piston head 30 than on the proximal side of piston head 30, thereby proximally propelling the piston head and the carrier. A vent tube between the proximal side of piston head 30 and outside the lumen may assist in creating the pressure difference across piston head 30, either passively, or actively via applied suction. Optionally, passageway 14 serves as the vent tube during withdrawal.

As seen in Fig. 5A, system 10 may eventually reach an obstacle or tight turn, indicated by arrow 62. In such a case, proximal piston head 46 may be inflated and distal piston head 30 may be deflated as shown in Fig. 5B. In this configuration, the pressurized fluid creates greater fluid pressure acting on the proximal side of proximal piston head 46 than on the distal side of proximal piston head 46. This pressure difference propels proximal piston head 46 together with carrier 26 distally, as indicated by arrow 64. This distal movement brings distal deflated piston head 30 past the obstacle,



as seen in Fig. 5B. System 10 continues its distal movement in body lumen 20 until proximal piston head 46 reaches the obstacle. At this point, distal piston head 30 may be inflated and proximal piston head 46 may be deflated once again, as shown in Fig. 5C. Once again, the pressurized fluid creates greater fluid pressure acting on the proximal side of distal piston head 30 than on the distal side of distal piston head 30. The pressure difference propels system 10 distally in body lumen 20, and brings proximal deflated piston head 46 past the obstacle. The cycle may be repeated as often as necessary.

Reference is now made to Fig. 6, which illustrates a system 68, constructed and operative in accordance with an embodiment of the present invention. System 68 operates in substantially the same manner as system 10, described hereinabove with reference to Figs. 1-4, in that distal piston head 30 is inflated until it is in contact with body lumen 20, such that a seal between piston head 30 and lumen 20 is formed. Pressurized fluid is then introduced via first passageway 14, producing a larger pressure on the proximal face of piston head 30 than on the distal face of piston head 30, resulting in a net force acting to move piston head 30 distally. A sufficient net pressure force results in distal movement of piston head 30 along with elongate carrier 26 and a tool 79. Tool 79 may comprise an imaging device, a biopsy device, or other apparatus to be used in body lumen 20.

Additionally, for some applications of the present invention, a suction source 78 is coupled to opening 40 via vent tube 38 to provide suction on the distal face of piston head 30 and facilitate the distal movement of piston head 30. Providing suction at opening 40 may also be used in some applications to remove contents of the lumen, such as excess fluid or stool, that are impeding the movement of piston head 30. For some applications, the suction decreases an accumulation of gas distal to piston head 30 that may be uncomfortable for the patient.

System 68 typically comprises one or more pressure sensors, for example in order to be able to improve or optimize the performance of the system with respect to ease and speed of movement of system 68 through lumen 20. In particular, system 68 typically comprises one or more of the following pressure sensors:

- a first pressure sensor 70, adapted to determine the pressure acting on the proximal face of distal piston 30;

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- a second pressure sensor 72, adapted to determine the inflation pressure of the distal piston head; and/or
- a third pressure sensor 74, adapted to determine the pressure acting on the distal face of piston head 30.

5       For some applications, the three pressure sensors are coupled to a pressure sensor bus 76, such that the various pressure readings can be sent to an electromechanical or mechanical control unit (not shown), which regulates the different pressures, either automatically or with input from the operator of the system. For some applications, only one of the pressure sensors is included in system 68 (e.g., sensor 70, sensor 72, or sensor  
10 74). For other applications, two of the pressure sensors are included, and one is omitted (e.g., sensor 70, sensor 72, or sensor 74).

      For some applications, first pressure sensor 70 is located proximal to distal piston head 30 in a vicinity of the piston head. Alternatively, first pressure sensor 70 is located in a vicinity of fluid pressure source 16, typically outside the body of the patient. In this  
15 latter configuration: (a) first pressure sensor 70 is integrated with pressure source 16, or is positioned separately from pressure source 16; and (b) first pressure sensor 70 is in fluid communication with a proximal portion of lumen 20 proximal to piston head 30, either via first passageway 14, or via a separate passageway in fluid communication with first pressure sensor 70 and the proximal portion of lumen 20 (separate passageway not  
20 shown). A distal end of such separate passageway is adapted to be positioned in the proximal portion of lumen 20, either in a vicinity of guide member 12, or more distally in lumen 20, such as in a vicinity of piston head 30 proximal to the piston head.

      For some applications, second pressure sensor 72 is located inside distal piston head 30. Alternatively, second pressure sensor 72 is located in a vicinity of fluid pressure  
25 source 36, typically outside the body of the patient. In this latter configuration, second pressure sensor 72 is in fluid communication with piston head 30, either via second passageway 34, or via a separate passageway in fluid communication with second pressure sensor 72 and piston head 30 (separate passageway not shown).

      For some applications, third pressure sensor 74 is located distal to distal piston  
30 head 30. Alternatively, third pressure sensor 74 is located in a vicinity of a proximal opening of vent tube 38 (which, for applications in which suction source 78 is provided,

is in a vicinity of the suction source), typically outside the body of the patient. In this latter configuration: (a) third pressure sensor 74 is integrated with suction source 78, or is positioned separately from suction source 78; and (b) third pressure sensor 74 is in fluid communication with a distal portion of lumen 20 distal to piston head 30, either via vent tube 38, or via a separate passageway in fluid communication with third pressure sensor 72 and the distal portion of lumen 20 (separate passageway not shown).

For some applications in which third pressure sensor 78 is in fluid communication with the distal portion of lumen 20 via vent tube 38, a source such as suction source 78 is adapted to periodically, such as once every 5 to 15 seconds, e.g., once every 10 seconds, generate a burst of fluid (i.e., liquid or gas) in vent tube 38, in order to clear from the tube any bodily material which may have entered the tube through opening 40. Similarly, for some applications in which third pressure sensor 78 is in fluid communication with the distal portion of lumen 20 via a separate passageway, an additional source of pressure coupled to a proximal end of the separate passageway periodically generates a burst of fluid in the separate passageway.

In some embodiments of the present invention, satisfactory performance of system 68 is attained by maintaining a pressure on the proximal side of piston head 30 at about 25 millibar gauge, a pressure on the distal side of piston head 30 at about 5 millibar gauge, and a pressure inside piston head 30 at about 20 millibar gauge. These values typically range, as appropriate, between about +10 and +50 millibar, -5 and +15 millibar, and +10 and +60 millibar, respectively.

For some applications, during distal advancement of system 68, the pressure inside piston head 30 is maintained within about 5 millibar of the pressure differential across either side of piston head 30. For example, using the exemplary numbers cited above, a pressured differential across the piston head is 25 millibar - 5 millibar = 20 millibar. By maintaining the pressure inside piston head 30 within 5 millibar of the pressure differential, the pressure inside piston head 30 would generally remain between 15 and 25 millibar. The pressure within piston head 30 is typically maintained near this differential pressure when piston head 30 comprises a flexible but substantially non-elastic material (e.g., a material such as a polyurethane that stretches less than 10% during inflation at less than 50 millibar). For embodiments in which piston head 30 comprises a flexible and elastic material (e.g., a material comprising silicone that stretches more than

10% during inflation at less than 50 millibar), the pressure within piston head 30 is typically greater than the differential pressure.

In an embodiment of the present invention, during distal advancement of system 68, the pressure inside piston head 30 is set to an initial value, such as between about 5 and 15 millibar, e.g., about 10 millibar. The pressure on the proximal side of piston head 30 is increased, typically gradually, and, simultaneously, the pressure inside piston head 30 is regulated to be the greater of (a) its initial value and (b) the pressure on the proximal side of piston head 30 plus a value such as a constant value. Typically, this constant value is between about 1 and about 5 millibar, e.g., between about 1.5 and about 2 millibar, such as about 2 millibar. Once system 68 begins advancing distally, the pressure on proximal head 30 generally declines or remains level, despite the continuous application of pressure by pressure source 16. A diameter of first passageway 14 is typically of a value sufficiently small to limit the increase over time of the pressure proximal to piston head 30 when system 68 is advancing distally. For example, the diameter of first passageway may be between about 3 and about 6 mm. In general, in this embodiment, substantially real-time control of the pressure in piston head 30 is exercised, while real-time control of the pressure in lumen 20 proximal to the piston head is not necessarily exercised.

Other combinations of the distal, proximal, and inside pressures for piston head 30 may be better suited for some applications, and the above numbers are not meant to limit the various operating pressures of embodiments of the current invention. Additionally, for some applications of the present invention, the various pressures acting on piston head 30 are regulated depending on where in the lumen the piston head is located.

Although Fig. 6 only shows a distal piston head, it is to be understood that the scope of the present invention includes a system comprising a proximal piston head, as shown in Fig. 1, comprising the various pressure control and measuring apparatus described hereinabove with regard to distal piston head 30 of Fig. 6.

Reference is now made to Fig. 7, which illustrates an inflatable piston head 80, constructed and operative in accordance with an embodiment of the present invention. Inflatable piston head 80 comprises an inflatable balloon that has the general form of a body of revolution about the axis formed by elongate carrier 26, wherein the distal end has a smaller diameter than the proximal end. Piston head 80 typically comprises a

material that is flexible but substantially inelastic in the range of pressures typically encountered, such that the shape of the piston head is not substantially changed by elastic deformation when the piston head is inflated. Alternatively, piston head 80 comprises a flexible and elastic material. In some embodiments of the present invention, inflatable piston head 80 has the shape of a cone, as shown in Fig. 7. It is noted that whereas a cone is formed by rotating a straight line about an axis of revolution, other shapes for inflatable piston head 80 are formed by rotating curved lines about an axis of revolution. For example, a parabola or circular arc may be used to generate appropriate shapes. In the context of the present patent application and in the claims, all such shapes which become narrower towards their distal end are referred to as having a "distally-narrowing portion."

For some embodiments of the present invention, the base of inflatable piston head 80 is flat. In some other embodiments, the base of inflatable piston head 80 is curved, wherein the curvature may be either concave or convex.

Fig. 8 shows an application of inflatable piston head 80, in accordance with an embodiment of the present invention. Piston head 80 is typically inserted into lumen 20 in a deflated state and subsequently inflated until appropriate contact is made with the lumen. Due to the shape of inflatable piston head 80, most of a fully-inflated portion 82 of the piston head is not in substantial contact with lumen 20, while a partially-inflated portion 84 of the piston head is in contact with lumen 20, once the piston head is fully pressurized. A good seal between piston head 80 and lumen 20 is typically obtained where fully-inflated portion 82 meets partially-inflated portion 84.

Figs. 9A and 9B show cross-sections of the fully-inflated portion and the partially-inflated portion, respectively, in accordance with an embodiment of the present invention. Resistance of lumen 20 to radial expansion prevents the entire piston head from fully inflating (e.g., as shown in Fig. 7). Thus, partially-inflated portion 84 typically becomes somewhat wrinkled along the length of its contact with lumen 20.

Inflatable piston head 80 is regulated to respond to changes in the diameter of lumen 20 by inflating more as the lumen diameter increases, and by deflating as the lumen diameter decreases, all while maintaining satisfactory contact with the lumen. Since inflatable piston head 80 is typically made of a substantially inelastic material, a relatively modest pressure is needed to inflate the piston head. The inflation pressure is

chosen to maintain an appropriate seal between the piston head and the lumen, without undue pressure on the lumen.

5 Figs. 10A and 10B are pictorial illustrations of a multi-lobed piston head 100 for use in body lumen 20, constructed and operative in accordance with an embodiment of the present invention. Except for differences as noted, apparatus and techniques described hereinabove with respect to other piston heads are typically adapted for use with piston head 100.

10 Piston head 100 comprises a distal lobe 102 and a proximal lobe 104. Lobes 102 and 104 articulate at an intermediate portion 106. In an embodiment, dimensions of piston head 100 include: (a) a diameter D1 of distal lobe 102, which is substantially equal to the diameter of lumen 20, so as to make a satisfactory seal therewith, (b) a diameter D2 of intermediate portion 106, ranging from about 10% to 40% of D1, and (c) a length D3 of distal lobe 102, ranging from about 3 to 5 cm. It is noted that although multi-lobed piston head 100 only comprises two lobes, the scope of the present invention includes  
15 multi-lobed piston heads having more lobes (e.g., 3, 4, or 5 lobes).

Distal and proximal lobes 102 and 104 are in fluid communication with each other through intermediate portion 106. In steady state, as well as at the levels of movement typically encountered during advancement through the colon, the pressure within lobe 102 is substantially the same as the pressure within lobe 104. Thus, passageway 34 and  
20 fluid pressure source 36 (Fig. 2) regulate the pressure within both lobes substantially simultaneously. The diameters of the two lobes, however, typically vary independently, in response to changes in the shape of lumen 20 adjacent to each of the lobes. Typically, as with all of the inflatable piston heads described herein, fluid is actively added to or removed from the piston head to maintain a generally constant pressure within the piston  
25 head.

In an embodiment of the present invention, piston head 30 and/or carrier 26 of system 10 and/or system 68 comprises a low friction coating, which acts to reduce the friction between piston head 30 and lumen 20, thereby easing the movement of piston head 30 and/or carrier 26 in lumen 20. For example, piston head 30 and/or carrier 26 may  
30 comprise a biocompatible low friction coating. Alternatively or additionally, piston head 30 and/or carrier 26 comprises a hydrophilic coating. Additionally or alternatively, the low friction coating comprises a suitable lubricant.

Figs. 11A and 11B are pictorial illustrations of multi-lobed piston head 100, in accordance with an embodiment of the present invention. In Figs. 11A and 11B, the following tubes described hereinabove are shown:

- second passageway 34 in fluid communication with both lobes 102 and 104 of piston head 100, connected to source of fluid pressure 36;
- vent tube 38, passing through lobes 102 and 104 of piston head 100, and having opening 40 distal to piston head 100 through which fluid is ventable to the outside;
- fluid supply tube 44, passing through piston head 100, for cleaning the area near image-capturing device 32, or in combination with vent tube 38, for cleaning body lumen 20 itself.

Second passageway 34, vent tube 38, and fluid supply tube 44 are typically flexible, which allows for the bending of piston head 100, as shown in Fig. 11B.

Fig. 12 is a schematic cross-sectional illustration of an optical system 220, in accordance with an embodiment of the present invention. For some applications, image-capturing device 32 comprises optical system 220. Optical system 220 comprises an optical assembly 230 and an image sensor 232, such as a CCD or CMOS sensor.

Optical system 220 is typically configured to enable simultaneous forward and omnidirectional lateral viewing. Light arriving from the forward end of an optical member 234, and light arriving from the lateral surface of the optical member travel through substantially separate, non-overlapping optical paths. The forward light and the lateral light are typically (but not necessarily) processed to create two separate images, rather than a unified image. For some applications, the forward view is used primarily for navigation within a body region, while the omnidirectional lateral view is used primarily for inspection of the body region.

Optical assembly 230 comprises, at a distal end thereof, a convex mirror 240 having a rotational shape that has the same rotation axis as optical member 234. Optical member 234 is typically shaped so as to define a distal indentation 244 at the distal end of the optical member, i.e., through a central portion of mirror 240. Alternatively, optical member 234 is shaped without indentation 244, but instead mirror 240 includes a non-mirrored portion in the center thereof.

Typically, optical assembly 230 further comprises a distal lens 252 that has the same rotation axis as optical member 234. For some applications, optical assembly 230 further comprises one or more proximal lenses 258, e.g., two proximal lenses 258. Proximal lenses 258 are positioned between optical member 234 and image sensor 232, so as to focus light from the optical member onto the image sensor.

For some applications, optical system 220 is configured to enable omnidirectional lateral viewing, without enabling forward viewing.

For some applications, a hydrophobic coating is applied to one or more of the transparent surfaces of optical assembly 220 that are in contact with body lumen 20.

Techniques described herein may be performed in combination with techniques described in US Provisional Patent Application 60/571,438, filed May 14, 2004, entitled, "Omnidirectional and forward-looking imaging device," which is assigned to the assignee of the present application and is incorporated herein by reference.

Reference is now made to Figs. 13A and 13B, which are pictorial illustrations of a system 310 (not to scale), in accordance with an embodiment of the present invention. System 310 is generally similar to system 10 and/or system 68, except as described hereinbelow. Image-capturing device 32 of system 310 typically comprises optical system 220, described hereinabove with reference to Fig. 12, or another omnidirectional imaging device. System 310 is typically advanced distally into lumen 20 using techniques described hereinabove with reference to systems 10 and/or 68.

System 310 is withdrawn in a proximal direction by: (a) inflating lumen 20, using conventional inflation techniques for withdrawing endoscopes, and (b) pulling carrier 26 in a proximal direction. During withdrawal, the distal end of the system sometimes comes near or in contact with the wall of lumen 20, as shown in Fig. 13A. For example, lumen 20 may be inflated to a diameter D1 of between about 40 and about 70 mm, and system 310 may have an initial distal diameter D2 in a vicinity of imaging-capturing device 32 of between about 8 and about 15 mm. When system 310 is near the wall of lumen 20, the distance between the lateral portion of optical system 220 of image-capturing device 32 may be less than the minimum focal length necessary for clear omnidirectional lateral viewing.



System 310 comprises an inflation element 320, which is adapted to increase the distal diameter of system 310 from D2 (Fig. 13A) to D3 (Fig. 13B). D3 is typically between about 30 and about 45 mm. This increased distal diameter ensures that image-capturing device 32 is a distance from the wall of lumen 20 sufficient to enable focusing of the omnidirectional lateral image. For example, this increased distal diameter may ensure that a central axis of image-capturing device 32 is at least a distance D4 of 15 mm from the wall of lumen 20. For some applications, inflation element 320 comprises a sponge, which expands, for example, when exposed to liquid. Alternatively, inflation element 320 comprises a set of inflatable or expandable rings. Further alternatively, inflation element 320 comprises an inflatable balloon, which is typically contained within the body of system 310.

Reference is now made to Fig. 14, which is a schematic illustration of an inserter 330 for use with system 10 and/or system 68, in accordance with an embodiment of the present invention. Inserter 330 is adapted to be at least partially insertable into proximal opening 18 (e.g., the rectum) of body lumen 20 (e.g., the colon). Inserter 330 typically comprises an annular ring 332 for abutting against proximal opening 18, and an annular balloon 336 that is coupled to ring 332. Ring 332 and balloon 336 are shaped so as to define a bore 334 through which carrier 26 is arranged for sliding movement. Balloon 336 expands to form a seal between the balloon and the wall of lumen 20 in a vicinity of proximal opening 18, thereby helping maintain positive pressure created within body lumen 20.

Inserter 330 comprises first passageway 14 connected to fluid pressure source 16 (as described hereinabove with reference to Figs. 1-3, for example), and a tube 338 for applying a positive pressure to inflate balloon 336. Tube 338 is connected to a fluid pressure source 340, which may comprise a powered fluid pressure source (such as is available in an operating room) or a manually-operated fluid pressure source (such as a syringe). When fluid pressure source 340 comprises a syringe, the syringe is typically removed after balloon 336 has been inflated, and tube 338 and/or balloon 336 is sealed to maintain the pressure, e.g., using a check valve (valve not shown). For some applications, pressure source 16 and pressure source 340 are derived from a common fluid pressure source.

Reference is now made to Fig. 15, which is a schematic illustration of a cleaning system 350 for use with system 10 and/or system 68, in accordance with an embodiment of the present invention. Cleaning system 350 is shaped to define one or more openings 360 (e.g., between about 4 and about 10) coupled to fluid supply tube 44. Openings 360 are disposed circumferentially about the distal end of carrier 26, and oriented so that they spray at least a portion of image-capturing device 32. For applications in which image-capturing device 32 comprises optical system 220, as described hereinabove with reference to Fig. 12, openings 360 are typically oriented to spray at least a portion of the lateral omnidirectional portion of optical assembly 230, and, optionally, a portion of the distal forward portion of the assembly. For some applications, openings 360 are positioned at a circumferential angle, so as to create a vortex around image-capturing device 32.

Although the piston head has been described in embodiments of the present invention as being in direct contact with the wall of the GI tract, the scope of the invention includes establishing contact between the piston head and the wall of the GI tract through an intermediary, such as a sheath surrounding the piston head.

Techniques described herein may be performed in conjunction with techniques described in the following patent applications, which are assigned to the assignee of the present application and are incorporated herein by reference: (a) US Patent Application 10/838,648 to Gross et al., entitled, "Pressure-propelled system for body lumen," filed May 3, 2004, and (b) a US provisional patent application to Gross et al., entitled, "Pressure-propelled system for body lumen," filed on or about January 9, 2004.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

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## CLAIMS

1. Apparatus for use with a biologically-compatible-fluid pressure source, comprising:
- 5 lumen;
- a piston head coupled to a distal portion of the carrier and adapted to:
- form a pressure seal with a wall of the lumen after
- the carrier has been inserted into the lumen, and
- be advanced distally through the body lumen in
- 10 response to pressure from the fluid pressure source,
- the apparatus being configured to facilitate distal advancement of the piston head by facilitating passage of fluid out of the lumen from a site within the lumen distal to the piston head; and
- 15 an optical system, coupled to the carrier in a vicinity of the distal portion, the optical system having distal and proximal ends, and comprising:
- an image sensor, positioned at the proximal end of the optical system;
- an optical member having distal and proximal ends,
- 20 and shaped so as to define a lateral surface, at least a distal portion of which is curved, configured to provide omnidirectional lateral viewing; and
- a convex mirror, coupled to the distal end of the optical member, wherein the optical member and the mirror
- 25 have respective rotational shapes about a common rotation axis.
2. The apparatus according to claim 1, wherein the lumen includes a gastrointestinal (GI) tract, and wherein the carrier is adapted to be inserted through the proximal opening of the GI tract.
- 30 3. The apparatus according to claim 2, wherein the GI tract includes a colon, and wherein the carrier is adapted to be inserted through the proximal opening of the colon.

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4. The apparatus according to claim 2, wherein the piston head is adapted to be in direct contact with the wall of the GI tract after the carrier has been inserted into the GI tract.
5. The apparatus according to claim 2, wherein the convex mirror is shaped so as to define an opening through which distal light can pass.
6. The apparatus according to claim 5, wherein the optical member is shaped so as to define a distal indentation in the distal end of the optical member.
7. The apparatus according to claim 5, wherein the optical member is shaped so as to define a proximal indentation in the proximal end of the optical member.
- 10 8. The apparatus according to claim 5, wherein the optical system comprises a distal lens, positioned distal to the mirror, the distal lens having a rotational shape about the common rotation axis.
9. The apparatus according to claim 5, wherein the optical system is configured to provide different levels of magnification for distal light arriving at the image sensor through the distal end of the optical system, and lateral light arriving at the image sensor through the curved distal portion of the lateral surface of the optical member.
- 15 10. The apparatus according to claim 2, wherein an outer surface of the piston head forming the pressure seal with the wall of the GI tract comprises a low friction coating suitable for facilitating sliding of the piston head against the wall of the GI tract.
- 20 11. The apparatus according to claim 2, comprising:  
a fluid source; and  
at least one fluid supply tube coupled to the carrier, the tube in fluid communication with the fluid source,  
wherein the distal portion of the carrier is shaped so as to define one or more  
25 openings in fluid communication with the tube, the openings oriented so as to spray at least a portion of the optical member when fluid is provided by the fluid source.
12. The apparatus according to claim 2, comprising an inflation element, fixed in a vicinity of the distal portion of the carrier, and adapted to increase a diameter of the carrier in the vicinity to an extent sufficient to position the optical member a distance  
30 from the wall sufficient to enable omnidirectional focusing of the optical system.

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13. The apparatus according to claim 2, comprising a vent tube, wherein the apparatus is adapted to facilitate the passage of the fluid out of the GI tract through the vent tube.
14. The apparatus according to claim 13, wherein the vent tube is adapted to passively permit the passage of the fluid out of the GI tract.
- 5 15. The apparatus according to claim 13, wherein the vent tube is adapted to be coupled to a suction source, whereby to actively facilitate the passage of the fluid out of the GI tract.
16. The apparatus according to claim 2, wherein the piston head is adapted to be inflated so as to form and maintain the pressure seal with the wall of the GI tract.
- 10 17. The apparatus according to claim 16, wherein the piston head is adapted to be intermittently deflated at least in part, while in the GI tract, whereby to facilitate the passage of the fluid out of the GI tract from the site within the GI tract distal to the piston head.
18. The apparatus according to claim 16, wherein the piston head is shaped to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.
- 15 19. The apparatus according to claim 16, comprising a piston-head-pressure sensor, adapted to sense a pressure within the piston head.
20. The apparatus according to claim 19, wherein the piston-head-pressure sensor is adapted to be disposed within the piston head.
- 20 21. The apparatus according to claim 19, wherein the piston-head-pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract.
22. The apparatus according to claim 21, wherein the piston-head-pressure sensor is adapted to be disposed outside of the GI tract.
23. Apparatus for use with a biologically-compatible-fluid pressure source, comprising:
- 25 an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and
- an inflatable piston head coupled to a distal portion of the carrier, the piston head shaped so as to define a proximal lobe and a distal lobe in fluid communication with each other, the piston head adapted to:
- 30

be inflated so as to form a pressure seal with a wall  
of the lumen after the carrier has been inserted into the  
lumen, and

5 be advanced distally through the body lumen in  
response to pressure from the fluid pressure source.

24. The apparatus according to claim 23, wherein the lumen includes a  
gastrointestinal (GI) tract, and wherein the carrier is adapted to be inserted through the  
proximal opening of the GI tract.

25. The apparatus according to claim 24, wherein the GI tract includes a colon, and  
10 wherein the carrier is adapted to be inserted through the proximal opening of the colon.

26. The apparatus according to claim 24, wherein the piston head is adapted to be in  
direct contact with the wall of the GI tract after the carrier has been inserted into the GI  
tract.

27. The apparatus according to claim 24,  
15 wherein a volume of a first one of the lobes is adapted to decrease in response to a  
constriction of the GI tract adjacent thereto,

wherein a volume of a second one of the lobes is adapted to remain constant in the  
absence of a change in GI tract diameter adjacent thereto, even if the volume of the first  
lobe is decreased, and

20 wherein a pressure within the first and second lobes is equal in steady state,  
regardless of the decrease in volume of the first lobe.

28. The apparatus according to claim 24, wherein the distal lobe has a diameter  
substantially equal to a diameter of the GI tract.

29. The apparatus according to claim 24, wherein the distal lobe has a length of  
25 between 3 and 5 cm.

30. The apparatus according to claim 24, wherein the piston head is shaped so as to  
define at least one lobe in addition to the first and second lobes.

31. The apparatus according to claim 24, wherein the piston head is shaped so as to  
define an intermediate portion at which the proximal and distal lobes articulate.

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32. The apparatus according to claim 31, wherein the intermediate portion has a diameter equal to between 10% and 40% of a diameter of the distal lobe.
33. The apparatus according to claim 24, comprising a flexible vent tube, passing through the proximal and distal lobes of the piston head, and opening to a site within the  
5 GI tract distal to the piston head, and adapted to facilitate distal advancement of the piston head by facilitating passage of fluid from the site.
34. The apparatus according to claim 33, comprising a suction source, adapted to actively facilitate the passage of the fluid from the site.
35. The apparatus according to claim 33,  
10 wherein a volume of a first one of the lobes is adapted to decrease in response to a constriction of the GI tract adjacent thereto,  
wherein a volume of a second one of the lobes is adapted to remain constant in the absence of a change in GI tract diameter adjacent thereto, even if the volume of the first lobe is decreased, and  
15 wherein a pressure within the first and second lobes is equal in steady state, regardless of the decrease in volume of the first lobe.
36. The apparatus according to claim 33, wherein the distal lobe has a diameter substantially equal to a diameter of the GI tract.
37. The apparatus according to claim 33, wherein the distal lobe has a length of  
20 between 3 and 5 cm.
38. The apparatus according to claim 33, wherein the piston head is shaped so as to define at least one lobe in addition to the first and second lobes.
39. The apparatus according to claim 33, wherein the piston head is shaped so as to define an intermediate portion at which the proximal and distal lobes articulate.
- 25 40. The apparatus according to claim 39, wherein the intermediate portion has a diameter equal to between 10% and 40% of a diameter of the distal lobe.
41. Apparatus comprising:  
an elongate carrier, adapted to be inserted through a proximal opening of a body lumen;

a balloon coupled to a distal portion of the carrier and adapted to be in direct contact with a wall of the lumen after the carrier has been inserted into the lumen; and  
a hydrophilic substance disposed at an external surface of the balloon.

42. The apparatus according to claim 41, wherein the lumen includes a gastrointestinal (GI) tract, and wherein the carrier is adapted to be inserted through the proximal opening of the GI tract.

43. The apparatus according to claim 42, wherein the GI tract includes a colon, and wherein the carrier is adapted to be inserted through the proximal opening of the colon.

44. The apparatus according to claim 42, wherein the balloon is shaped so as to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

45. Apparatus comprising:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

a balloon coupled to a distal portion of the carrier and adapted to be in direct contact with a wall of the lumen after the carrier has been inserted into the lumen, an outer surface of the balloon in contact with the wall of the lumen comprising a low friction coating suitable for facilitating sliding of the balloon against the wall of the lumen.

46. The apparatus according to claim 45, wherein the lumen includes a gastrointestinal (GI) tract, and wherein the carrier is adapted to be inserted through the proximal opening of the GI tract.

47. The apparatus according to claim 46, wherein the GI tract includes a colon, and wherein the carrier is adapted to be inserted through the proximal opening of the colon.

48. The apparatus according to claim 46, wherein the low friction coating comprises a lubricant.

49. The apparatus according to claim 46, wherein the balloon is shaped so as to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

50. Apparatus comprising:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and



a balloon coupled to a distal portion of the carrier and adapted to be in direct contact with a wall of the lumen after the carrier has been inserted into the lumen, the balloon having a characteristic thickness of no more than 20 microns.

51. The apparatus according to claim 50, wherein the lumen includes a gastrointestinal (GI) tract, and wherein the carrier is adapted to be inserted through the proximal opening of the GI tract.

52. The apparatus according to claim 51, wherein the GI tract includes a colon, and wherein the carrier is adapted to be inserted through the proximal opening of the colon.

53. The apparatus according to claim 51, wherein the balloon has a characteristic thickness of no more than 10 microns.

54. The apparatus according to claim 51, wherein an outer surface of the balloon in contact with the wall of the GI tract comprises a low friction coating suitable for facilitating sliding of the balloon against the wall of the GI tract.

55. The apparatus according to claim 51, wherein an outer surface of the balloon in contact with the wall of the GI tract comprises a hydrophilic substance suitable for facilitating sliding of the balloon against the wall of the GI tract.

56. The apparatus according to claim 51, wherein the balloon is shaped so as to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

57. Apparatus for use with a biologically-compatible-fluid pressure source, comprising:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

a piston head coupled to a distal portion of the carrier and adapted to:

form a pressure seal with a wall of the lumen after the carrier has been inserted into the lumen, and

be withdrawn proximally through the body lumen in response to pressure from the fluid pressure source.

58. The apparatus according to claim 57, wherein the lumen includes a gastrointestinal (GI) tract, and wherein the piston head is adapted to form the pressure seal with the wall of the GI tract after the carrier has been inserted into the GI tract.

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59. The apparatus according to claim 58, wherein the GI tract includes a colon, and wherein the piston head is adapted to form the pressure seal with the wall of the colon after the carrier has been inserted into the colon.

60. The apparatus according to claim 58, wherein the piston head is adapted to be in direct contact with the wall of the GI tract after the carrier has been inserted into the GI tract.

61. The apparatus according to claim 58, wherein an outer surface of the piston head forming the pressure seal with the wall of the GI tract comprises a low friction coating suitable for facilitating sliding of the piston head against the wall of the GI tract.

62. The apparatus according to claim 58, wherein the piston head is shaped so as to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

63. The apparatus according to claim 58, comprising a pressure-application tube in fluid communication with (a) a distal site within the GI tract distal to the piston head, and (b) the fluid pressure source, the tube adapted to introduce the pressure to the distal site.

64. The apparatus according to claim 58, comprising:

a fluid source;

an image-capturing device, coupled to the carrier in a vicinity of a distal end of the carrier; and

at least one fluid supply tube coupled to the carrier, the tube in fluid communication with the fluid source,

wherein the distal end of the carrier is shaped so as to define one or more openings in fluid communication with the tube, the openings oriented so as to spray at least a portion of the image-capturing device when fluid is provided by the fluid source.

65. The apparatus according to claim 58, wherein the apparatus is adapted to facilitate passage of fluid out of the GI tract from a proximal site within the GI tract proximal to the piston head.

66. The apparatus according to claim 65, comprising a vent tube in fluid communication with the proximal site and outside the GI tract, the tube adapted to facilitate passage of fluid from the proximal site to the outside, so as to reduce a pressure at the proximal site.

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67. The apparatus according to claim 66, wherein the vent tube is adapted to passively permit the passage of the fluid from the proximal site.
68. The apparatus according to claim 66, comprising a suction source coupled to the vent tube, adapted to actively facilitate the passage of the fluid from the proximal site.
- 5 69. The apparatus according to claim 58, wherein the piston head is adapted to be inflated so as to form and maintain the pressure seal with the wall of the GI tract.
70. The apparatus according to claim 69, comprising a piston-head-pressure sensor, adapted to sense a pressure within the piston head.
71. The apparatus according to claim 70, wherein the piston-head-pressure sensor is  
10 adapted to be disposed within the piston head.
72. The apparatus according to claim 70, wherein the piston-head-pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract.
73. The apparatus according to claim 72, wherein the piston-head-pressure sensor is adapted to be disposed outside of the GI tract.
- 15 74. The apparatus according to claim 69, comprising a distal pressure sensor, adapted to sense a pressure within the GI tract distal to the piston head.
75. The apparatus according to claim 74, wherein the distal pressure sensor is adapted to be disposed distal to the piston head.
76. The apparatus according to claim 74, wherein the distal pressure sensor is adapted  
20 to be disposed in a vicinity of the proximal opening of the GI tract.
77. The apparatus according to claim 76, wherein the distal pressure sensor is adapted to be disposed outside of the GI tract.
78. The apparatus according to claim 69, comprising a proximal pressure sensor, adapted to sense a pressure within the GI tract proximal to the piston head.
- 25 79. The apparatus according to claim 78, wherein the proximal pressure sensor is adapted to be disposed in a vicinity of the piston head.
80. The apparatus according to claim 78, wherein the proximal pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract.

81. The apparatus according to claim 80, wherein the proximal pressure sensor is adapted to be disposed outside of the GI tract.

82. The apparatus according to claim 69, comprising:

5 a pressure sensor, adapted to measure a first pressure associated with operation of the apparatus; and

a control unit, adapted to regulate a second pressure associated with operation of the apparatus responsive to the measurement of the pressure sensor.

83. The apparatus according to claim 82, wherein the pressure sensor is adapted to measure a pressure selected from the list consisting of: a pressure distal to the piston head, a pressure proximal to the piston head, and a pressure within the piston head.

84. Apparatus comprising:

an elongate carrier adapted to be inserted through a proximal opening of a body lumen;

15 an annular balloon, shaped so as to form an opening therethrough for insertion of the carrier, the balloon adapted to be at least partially inserted into the proximal opening, and to be expandable to form a pressure seal between the balloon and a wall of the body lumen in a vicinity of the proximal opening;

first and second fluid pressure sources;

20 a first tube, coupled between the first pressure source and an interior of the balloon; and

a second tube, coupled between the second pressure source and an interior of the lumen distal to the annular balloon.

85. The apparatus according to claim 84, wherein the body lumen includes a colon, wherein the proximal opening includes a rectum, and wherein the balloon is adapted to be at least partially inserted into the rectum, and to be expandable to form the pressure seal between the balloon and the wall of the colon.

86. The apparatus according to claim 85, wherein at least one of the first and second pressure sources is adapted to be positioned outside the colon.

87. The apparatus according to claim 85, comprising a ring coupled to the balloon, the ring adapted to abut against the rectum, and the ring shaped so as to form an opening therethrough for insertion of the carrier.

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88. The apparatus according to claim 85, wherein the first pressure source comprises a powered fluid pressure source.

89. The apparatus according to claim 85, wherein the first pressure source comprises a manually-operated fluid pressure source.

5 90. The apparatus according to claim 89, wherein the manually-operated pressure source comprises a syringe.

91. Apparatus comprising:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and

10 an inflatable cuff, shaped so as to define an opening therethrough through which the carrier can be inserted, the cuff adapted to form a pressure seal with a wall of the body lumen when the cuff is in an inflated state in a vicinity of the proximal opening.

92. The apparatus according to claim 91, wherein the body lumen includes a colon, wherein the proximal opening includes a rectum, and wherein the carrier is adapted to be  
15 inserted through the rectum of the colon.

93. Apparatus for use with a fluid source, the apparatus comprising:

an elongate carrier, adapted to be inserted through a proximal opening of a body lumen;

an image-capturing device, fixed to the carrier in a vicinity of a distal end of the  
20 carrier; and

at least one fluid supply tube coupled to the carrier, the tube in fluid communication with the fluid source,

wherein the distal end of the carrier is shaped so as to define one or more openings in fluid communication with the tube, the openings oriented so as to spray at least a  
25 portion of the image-capturing device when fluid is provided by the fluid source.

94. The apparatus according to claim 93, wherein the body lumen includes a colon, and wherein the carrier is adapted to be inserted through the proximal opening of the colon.

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95. The apparatus according to claim 94, wherein the distal end of the carrier is shaped so as to define between 4 and 10 openings through which the fluid flows when provided by the fluid source.

5 96. The apparatus according to claim 94, wherein the openings are disposed circumferentially about the distal end of the carrier.

97. The apparatus according to claim 94, wherein the openings are positioned at a circumferential angle, so as to create a vortex around the image-capturing device when the fluid is provided by the fluid source.

10 98. The apparatus according to claim 94, wherein the image-capturing device comprises an optical member that is shaped so as to define a lateral surface configured to provide omnidirectional lateral viewing, and wherein the openings are oriented so as to spray at least a portion of the lateral surface of the optical member.

15 99. The apparatus according to claim 98, wherein the optical member is shaped so as to define a forward surface configured to provide forward viewing, and wherein the openings are oriented so as to spray at least a portion of the forward surface of the optical member.

100. Apparatus for use in a body lumen having a proximal opening, the apparatus comprising:

20 an elongate carrier, adapted to be inserted through the proximal opening of the lumen;

an image-capturing device, fixed in a first vicinity of a distal end of the carrier, and adapted to provide omnidirectional lateral viewing; and

25 an inflation element, fixed in a second vicinity of the distal end, and adapted to increase a diameter of the carrier in the second vicinity to an extent sufficient to position the image-capturing device a distance from a wall of the lumen sufficient to enable omnidirectional focusing of the image-capturing device.

101. The apparatus according to claim 100, wherein the lumen includes a gastrointestinal (GI) tract, and wherein the carrier is adapted to be inserted through the proximal opening of the GI tract.

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102. The apparatus according to claim 101, wherein the inflation element is adapted to increase the diameter of the carrier in the second vicinity such that the image-capturing device is at least 15 mm from the wall.

5 103. The apparatus according to claim 101, wherein the inflation element comprises an expandable sponge.

104. The apparatus according to claim 101, wherein the inflation element comprises a set of one or more rings, selected from the list consisting of: inflatable rings, and expandable rings.

10 105. The apparatus according to claim 101, wherein the inflation element comprises an inflatable balloon.

106. The apparatus according to claim 101, wherein the GI tract includes a colon, and wherein the carrier is adapted to be inserted through the proximal opening of the colon.

107. The apparatus according to claim 106, wherein the inflation element is adapted to increase the diameter of the carrier in the second vicinity to between 30 and 45 mm.

15 108. Apparatus for use in a body lumen having a proximal opening, the apparatus comprising:

first and second fluid pressure sources;

an elongate carrier, adapted to be inserted through the proximal opening of the body lumen;

20 an inflatable piston head coupled to a distal portion of the carrier, and adapted to form a pressure seal with a wall of the lumen after the carrier has been inserted into the lumen;

a first passageway in fluid communication with the first pressure source and a proximal portion of the lumen proximal to the piston head;

25 a second passageway in fluid communication with the second pressure source and the piston head;

first and second pressure sensors, adapted to measure a first measurable pressure in the proximal portion of the lumen, and a second measurable pressure in the piston head, respectively; and

30 a control unit, adapted to cause the piston head to be advanced distally in the lumen by:

while the first pressure source applies a first applied pressure to the proximal portion of the lumen,

regulating the second measurable pressure in the piston head to be equal to the first measurable pressure in the proximal portion of the lumen plus a positive value, by driving the second pressure source to apply a second applied pressure.

5

109. The apparatus according to claim 108, wherein the lumen includes a gastrointestinal (GI) tract, and wherein the carrier is adapted to be inserted through the proximal opening of the GI tract.

110. The apparatus according to claim 109, wherein the GI tract includes a colon, and wherein the carrier is adapted to be inserted through the proximal opening of the colon.

10

111. The apparatus according to claim 109, wherein the piston is adapted to be in direct contact with the wall of the GI tract after the carrier has been inserted into the GI tract.

112. The apparatus according to claim 109, comprising a third passageway in fluid communication with a portion of the GI tract distal to the piston head and a site outside the GI tract.

15

113. The apparatus according to claim 109, wherein the first passageway has a diameter of between 3 and 6 mm.

114. The apparatus according to claim 109, wherein the first pressure sensor is adapted to be disposed in a vicinity of the piston head.

115. The apparatus according to claim 109, wherein the first pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract.

20

116. The apparatus according to claim 115, wherein the first pressure sensor is adapted to be disposed outside of the GI tract.

117. The apparatus according to claim 109, wherein the second pressure sensor is adapted to be disposed within the piston head.

25

118. The apparatus according to claim 109, wherein the second pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract.

119. The apparatus according to claim 118, wherein the second pressure sensor is adapted to be disposed outside of the GI tract.



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120. The apparatus according to claim 109, wherein the positive value is between 1 and 5 millibar.
121. The apparatus according to claim 120, wherein the positive value is between 1.5 and 2.5 millibar.
- 5 122. The apparatus according to claim 109, wherein the control unit is adapted to set the second measurable pressure in the piston head at an initial value prior to application of the first applied pressure, by driving the second pressure source to apply the second applied pressure.
123. The apparatus according to claim 122, wherein the initial value is between 5 and 10 15 millibar, and wherein the control unit is adapted to set the second measurable pressure at between 5 and 15 millibar.
124. The apparatus according to claim 122, wherein the control unit is adapted to regulate the second measurable pressure to be equal to the greater of: (a) the initial value, and (b) the first measurable pressure plus the positive value.
- 15 125. Apparatus for use with a biologically-compatible-fluid pressure source, comprising:  
an elongate carrier, adapted to be inserted through a proximal opening of a body lumen; and  
a distal piston head coupled to a distal portion of the carrier and adapted to:  
20 form a pressure seal with a wall of the lumen after the carrier has been inserted into the lumen, and  
be advanced distally through the body lumen in response to pressure from the fluid pressure source applied to an external surface of the distal piston head.
126. The apparatus according to claim 125, wherein the lumen includes a 25 gastrointestinal (GI) tract, and wherein the distal piston head is adapted to form the pressure seal with the wall of the GI tract after the carrier has been inserted into the GI tract.
127. The apparatus according to claim 126, wherein the GI tract includes a colon, and wherein the distal piston head is adapted to form the pressure seal with the wall of the 30 colon after the carrier has been inserted into the colon.

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128. The apparatus according to claim 126, wherein the distal piston head is adapted to be in direct contact with the wall of the GI tract after the carrier has been inserted into the GI tract.

129. The apparatus according to claim 126, wherein an outer surface of the distal piston head forming the pressure seal with the wall of the GI tract comprises a low friction coating suitable for facilitating sliding of the distal piston head against the wall of the GI tract.

130. The apparatus according to claim 126, comprising:  
a fluid source;  
an optical member coupled in a vicinity of the distal portion of the carrier; and  
at least one fluid supply tube coupled to the carrier, the tube in fluid communication with the fluid source,

wherein the distal portion of the carrier is shaped so as to define one or more openings in fluid communication with the tube, the openings oriented so as to spray at least a portion of the optical member when fluid is provided by the fluid source.

131. The apparatus according to claim 126, comprising:  
an optical system comprising an optical member configured to provide omnidirectional lateral viewing; and  
an inflation element, fixed in a vicinity of the distal portion of the carrier, and adapted to increase a diameter of the carrier in the vicinity to an extent sufficient to position the optical member a distance from the wall sufficient to enable omnidirectional focusing of the optical system.

132. The apparatus according to claim 126, wherein the apparatus is adapted to facilitate distal advancement of the distal piston head by facilitating passage of fluid out of the GI tract from a distal site within the GI tract distal to the distal piston head.

133. The apparatus according to claim 132, wherein the apparatus is adapted to facilitate the passage of an amount of the fluid out of the GI tract from the distal site sufficient to maintain a pressure of less than 10 millibar at the distal site.

134. The apparatus according to claim 132, wherein the apparatus is adapted to facilitate the passage of at least 100 cc of the fluid out of the GI tract from the distal site, per minute that the distal piston head advances distally.

135. The apparatus according to claim 134, wherein the apparatus is adapted to facilitate the passage of at least 300 cc of the fluid out of the GI tract from the distal site, per minute that the distal piston head advances distally.
136. The apparatus according to claim 132, wherein the apparatus is adapted to facilitate the passage of at least 3 cc of the fluid out of the GI tract from the distal site, per centimeter that the distal piston head advances distally.
137. The apparatus according to claim 136, wherein the apparatus is adapted to facilitate the passage of at least 10 cc of the fluid out of the GI tract from the distal site, per centimeter that the distal piston head advances distally.
138. The apparatus according to claim 132, comprising a vent tube, wherein the apparatus is adapted to facilitate the passage of the fluid out of the GI tract from the distal site within the GI tract through the vent tube.
139. The apparatus according to claim 138, wherein the vent tube is shaped to define an inner diameter thereof that is between 1 and 3 millimeters.
140. The apparatus according to claim 138, wherein the vent tube is adapted to passively permit the passage of the fluid out of the GI tract from the distal site within the GI tract.
141. The apparatus according to claim 138, wherein the vent tube is adapted to be coupled to a suction source, whereby to actively facilitate the passage of the fluid out of the GI tract from the distal site within the GI tract.
142. The apparatus according to claim 141, wherein the vent tube is adapted to be coupled to the suction source such that during operation of the apparatus, a pressure distal to the distal piston head is between -5 millibar and +15 millibar.
143. The apparatus according to claim 138, comprising a suction source coupled to the vent tube, adapted to actively facilitate the passage of the fluid out of the GI tract from the distal site within the GI tract.
144. The apparatus according to claim 143, wherein the suction source is adapted to maintain a pressure distal to the distal piston head is between -5 millibar and +15 millibar.
145. The apparatus according to claim 132, wherein the distal piston head is adapted to be inflated so as to form and maintain the pressure seal with the wall of the GI tract, and

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wherein the distal piston head is adapted to be intermittently deflated at least in part, while in the GI tract, whereby to facilitate the passage of the fluid out of the GI tract from the site within the GI tract distal to the distal piston head.

146. The apparatus according to claim 126, wherein the distal piston head is adapted to be inflated so as to form and maintain the pressure seal with the wall of the GI tract.

147. The apparatus according to claim 146, comprising an auxiliary piston head, coupled to the carrier at a position proximal to the distal piston head,

wherein the auxiliary piston head is adapted to be inflated so as to form and maintain an auxiliary pressure seal with the wall of the GI tract, and

10 wherein:

(a) at at least one time while the carrier is within the GI tract, the distal piston head is adapted to be in a state of being already deflated at least in part, simultaneously with the auxiliary piston head being already inflated and being advanced distally through the GI tract in response to pressure from the fluid pressure source, and

(b) at at least one other time while the carrier is within the GI tract, the auxiliary piston head is adapted to be in a state of being already deflated at least in part, simultaneously with the distal piston head being already inflated and being advanced distally through the GI tract in response to pressure from the fluid pressure source.

148. The apparatus according to claim 146, comprising a piston-head-pressure sensor, adapted to sense a pressure within the distal piston head.

149. The apparatus according to claim 148, wherein the piston-head-pressure sensor is adapted to be disposed within the distal piston head.

150. The apparatus according to claim 148, wherein the piston-head-pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract.

151. The apparatus according to claim 150, wherein the piston-head-pressure sensor is adapted to be disposed outside of the GI tract.

152. The apparatus according to claim 146, comprising a distal pressure sensor, adapted to sense a pressure within the GI tract distal to the distal piston head.

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153. The apparatus according to claim 152, wherein the distal pressure sensor is adapted to be disposed distal to the distal piston head.
154. The apparatus according to claim 152, wherein the distal pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract.
- 5 155. The apparatus according to claim 154, wherein the distal pressure sensor is adapted to be disposed outside of the GI tract.
156. The apparatus according to claim 146, comprising a proximal pressure sensor, adapted to sense a first measurable pressure, within a proximal portion of the GI tract proximal to the distal piston head.
- 10 157. The apparatus according to claim 156, comprising a distal pressure sensor, adapted to sense a pressure distal to the distal piston head.
158. The apparatus according to claim 156, wherein the proximal pressure sensor is adapted to be disposed in a vicinity of the distal piston head.
159. The apparatus according to claim 156, wherein the proximal pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract.
- 15 160. The apparatus according to claim 159, wherein the proximal pressure sensor is adapted to be disposed outside of the GI tract.
161. The apparatus according to claim 156, comprising a piston-head-pressure sensor, adapted to sense a second measurable pressure, within the distal piston head.
- 20 162. The apparatus according to claim 161, wherein the pressure source includes a first pressure source, adapted to apply a first applied pressure to the proximal portion of the GI tract, and comprising:
- a second pressure source, adapted to apply a second applied pressure to an interior of the distal piston head; and
  - 25 a control unit, adapted to advance the distal piston head distally in the GI tract by:
    - while the first pressure source applies the first applied pressure to the proximal portion,
    - regulating the second measurable pressure in the distal piston head to be equal to the first measurable pressure in the proximal portion of the GI tract plus a

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positive value, by driving the second pressure source to apply the second applied pressure.

163. The apparatus according to claim 146, comprising:

5 a pressure sensor, adapted to measure a first pressure associated with operation of the apparatus; and

a control unit, adapted to regulate a second pressure associated with operation of the apparatus responsive to the measurement of the pressure sensor.

164. The apparatus according to claim 163, wherein the pressure sensor is adapted to measure a pressure selected from the list consisting of: a pressure distal to the distal  
10 piston head, a pressure proximal to the distal piston head, and a pressure within the distal piston head.

165. The apparatus according to claim 163, wherein the control unit is adapted to regulate the pressure being measured by the pressure sensor.

166. The apparatus according to claim 163, wherein the control unit is adapted to  
15 regulate a pressure other than that being measured by the pressure sensor.

167. The apparatus according to claim 146, wherein the distal piston head is shaped to define a proximal lobe and a distal lobe, the lobes being in fluid communication with each other.

168. The apparatus according to claim 167,  
20 wherein a volume of a first one of the lobes is adapted to decrease in response to a constriction of the GI tract adjacent thereto,

wherein a volume of a second one of the lobes is adapted to remain constant in the absence of a change in GI tract diameter adjacent thereto, even if the volume of the first lobe is decreased, and

25 wherein a pressure within the first and second lobes is equal in steady state, regardless of the decrease in volume of the first lobe.

169. The apparatus according to claim 146, wherein the distal piston head is adapted to be at an inflation pressure between 10 and 60 millibar during advancement through the GI tract.

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170. The apparatus according to claim 169, wherein the distal piston head is adapted to advance through the GI tract in response to a pressure from the fluid pressure source that is between 30% and 100% of the inflation pressure.

5 171. The apparatus according to claim 170, wherein the distal piston head is adapted to advance through the GI tract in response to a pressure from the fluid pressure source that is between 50% and 100% of the inflation pressure.

172. The apparatus according to claim 169, wherein the distal piston head is adapted to be at an inflation pressure between 20 and 50 millibar during advancement through the GI tract.

10 173. The apparatus according to claim 172, wherein the distal piston head is adapted to be at an inflation pressure between 30 and 45 millibar during advancement through the GI tract.

174. The apparatus according to claim 173, wherein the distal piston head is adapted to advance through the GI tract in response to a pressure from the fluid pressure source that  
15 is between 30% and 100% of the inflation pressure.

175. The apparatus according to claim 174, wherein the distal piston head is adapted to advance through the GI tract in response to a pressure from the fluid pressure source that is between 50% and 100% of the inflation pressure.

20 176. The apparatus according to claim 175, wherein the distal piston head is adapted to advance through the GI tract in response to a pressure from the fluid pressure source that is between 50% and 80% of the inflation pressure.

177. The apparatus according to claim 146, wherein the distal piston head is shaped to define a distally-narrowing portion, and is adapted to be inserted into the GI tract such that a tip of the distally-narrowing portion points in a distal direction when the distal  
25 piston head is in the GI tract.

178. The apparatus according to claim 177, wherein a proximal base of the distally-narrowing portion has a characteristic fully-inflated diameter that is larger than a diameter of at least a part of the GI tract through which the distally-narrowing portion is adapted to pass, whereby the base of the distally-narrowing portion does not inflate fully when the  
30 base is in that part of the GI tract.

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179. Apparatus for use in a body lumen having a proximal opening, the apparatus comprising:

an elongate carrier, adapted to be inserted through the proximal opening of the body lumen;

5 an inflatable piston head coupled to a distal portion of the carrier, and adapted to form a pressure seal with a wall of the lumen after the carrier has been inserted into the lumen; and

a biologically-compatible fluid proximal pressure source, adapted to be in fluid communication with a proximal portion of the lumen proximal to the piston head, and to  
10 apply pressure sufficient to advance the carrier distally through the body lumen.

180. The apparatus according to claim 179, wherein the lumen includes a gastrointestinal (GI) tract, and wherein the piston head is adapted to form the pressure seal with the wall of the GI tract.

181. The apparatus according to claim 180, wherein the GI tract includes a colon, and  
15 wherein the piston head is adapted to form the pressure seal with the wall of the colon.

182. The apparatus according to claim 180, wherein the piston head is adapted to be in direct contact with the wall of the GI tract.

183. The apparatus according to claim 180, comprising a first passageway, wherein the proximal pressure source is in the fluid communication with the proximal portion of the  
20 GI tract via the first passageway.

184. The apparatus according to claim 180, comprising a piston pressure source, adapted to be in fluid communication with the piston head, and to apply pressure to the piston head in order to inflate the piston head.

185. The apparatus according to claim 184, comprising a second passageway, wherein  
25 the piston pressure source is in the fluid communication with the piston head via the second passageway.

186. The apparatus according to claim 180, comprising:

a proximal pressure sensor, adapted to measure a pressure in the proximal portion of the GI tract; and

30 a piston pressure sensor, adapted to measure a pressure in the piston head.



187. The apparatus according to claim 180, comprising a proximal pressure sensor, adapted to measure a pressure in the proximal portion of the GI tract.
188. The apparatus according to claim 187, wherein the proximal pressure sensor is adapted to be disposed in a vicinity of the piston head.
- 5 189. The apparatus according to claim 187, wherein the proximal pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract.
190. The apparatus according to claim 189, wherein the proximal pressure sensor is adapted to be disposed outside of the GI tract.
191. The apparatus according to claim 180, comprising a piston pressure sensor,  
10 adapted to measure a pressure in the piston head.
192. The apparatus according to claim 191, wherein the piston pressure sensor is adapted to be disposed within the piston head.
193. The apparatus according to claim 191, wherein the piston pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract.
- 15 194. The apparatus according to claim 193, wherein the piston pressure sensor is adapted to be disposed outside of the GI tract.
195. The apparatus according to claim 180, comprising a vent tube, adapted to:  
be in fluid communication with a distal portion of the GI tract distal to the piston head, and with outside of the GI tract, and  
20 facilitate distal advancement of the piston head by facilitating passage of fluid out of the GI tract from the distal portion.
196. The apparatus according to claim 195, comprising a distal pressure sensor, adapted to measure a pressure in the distal portion of the GI tract.
197. The apparatus according to claim 196, wherein the distal pressure sensor is  
25 adapted to be disposed distal to the piston head.
198. The apparatus according to claim 196, wherein the distal pressure sensor is adapted to be disposed in a vicinity of the proximal opening of the GI tract.
199. The apparatus according to claim 198, wherein the distal pressure sensor is adapted to be disposed outside of the GI tract.

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200. The apparatus according to claim 195, wherein the apparatus is adapted to facilitate the passage of an amount of the fluid out of the GI tract from the distal portion sufficient to maintain a pressure of less than 10 millibar at the distal portion.

201. The apparatus according to claim 195, wherein the vent tube is adapted to passively permit the passage of the fluid out of the GI tract from the distal portion.

202. The apparatus according to claim 195, comprising a suction source coupled to the vent tube, adapted to actively facilitate the passage of the fluid out of the GI tract from the distal portion.

203. The apparatus according to claim 195, wherein the apparatus is adapted to facilitate the passage of at least 100 cc of the fluid out of the GI tract from the distal portion, per minute that the piston head advances distally.

204. The apparatus according to claim 203, wherein the apparatus is adapted to facilitate the passage of at least 300 cc of the fluid out of the GI tract from the distal portion, per minute that the piston head advances distally.

205. The apparatus according to claim 195, wherein the apparatus is adapted to facilitate the passage of at least 3 cc of the fluid out of the GI tract from the distal portion, per centimeter that the piston head advances distally.

206. The apparatus according to claim 205, wherein the apparatus is adapted to facilitate the passage of at least 10 cc of the fluid out of the GI tract from the distal portion, per centimeter that the piston head advances distally.

207. Apparatus for use in a body lumen having a proximal opening, the apparatus comprising:

an elongate carrier, adapted to be inserted through the proximal opening of the body lumen;

an inflatable piston head coupled to a distal portion of the carrier, and adapted to form a pressure seal with a wall of the lumen after the carrier has been inserted into the lumen;

a biologically-compatible fluid proximal pressure source, adapted to be in fluid communication with a proximal portion of the lumen proximal to the piston head, and to apply pressure sufficient to advance the carrier distally through the body lumen; and

a piston head pressure sensor, adapted to sense a piston head pressure in the piston head, the piston head pressure sensor disposed in a vicinity of the proximal opening of the lumen, and in fluid communication with an interior of the piston head.

5 208. The apparatus according to claim 207, wherein the lumen includes a gastrointestinal (GI) tract, and wherein the piston head is adapted to form the pressure seal with the wall of the GI tract.

209. The apparatus according to claim 208, wherein the GI tract includes a colon, and wherein the piston head is adapted to form the pressure seal with the wall of the colon.

10 210. The apparatus according to claim 208, wherein the piston head is adapted to be in direct contact with the wall of the GI tract.

211. The apparatus according to claim 208, wherein the piston head pressure sensor is adapted to be in fluid communication with the interior of the piston head via a passageway, a proximal end of which is disposed in the vicinity of the proximal opening of the GI tract.

15 212. The apparatus according to claim 208, wherein the piston head pressure sensor is adapted to be disposed outside of the GI tract.

213. The apparatus according to claim 208, comprising a biologically-compatible fluid piston head pressure source, adapted to be in fluid communication with the interior of the piston head via a passageway, wherein the piston head pressure sensor is adapted to be in  
20 fluid communication with the interior of the piston head via the passageway.

214. The apparatus according to claim 208, comprising a proximal portion pressure sensor, adapted to sense a proximal portion pressure in the proximal portion of the GI tract, and disposed in a vicinity of the proximal opening of the GI tract.

25 215. The apparatus according to claim 214, wherein the proximal portion pressure sensor is adapted to be disposed outside of the GI tract.

216. The apparatus according to claim 208, comprising a distal portion pressure sensor, adapted to sense a distal portion pressure in a distal portion of the GI tract distal to the piston head, and disposed in a vicinity of the proximal opening of the GI tract.

30 217. The apparatus according to claim 216, wherein the distal portion pressure sensor is adapted to be disposed outside of the GI tract.

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218. A method comprising:  
forming a pressure seal between a piston head and a wall of a body lumen;  
advancing the piston head distally through the body lumen by:  
applying fluid pressure to an external surface of the piston  
5 head, and  
facilitating passage of fluid out of the lumen from a site  
within the lumen distal to the piston head; and  
providing omnidirectional lateral viewing from a vicinity of the piston head.
219. The method according to claim 218, wherein the lumen includes a gastrointestinal  
10 (GI) tract, and wherein forming the pressure seal comprises forming the pressure seal  
between the piston head and the wall of the GI tract.
220. The method according to claim 219, wherein the GI tract includes a colon, and  
wherein forming the pressure seal comprises forming the pressure seal between the piston  
head and the wall of the colon.
- 15 221. The method according to claim 219, wherein forming the pressure seal comprises  
placing the piston head in direct contact with the wall of the GI tract.
222. The method according to claim 219, comprising providing distal forward viewing  
from the vicinity of the piston head.
223. The method according to claim 219, wherein facilitating the passage of the fluid  
20 out of the GI tract comprises facilitating the passage of the fluid out of the GI tract  
through a vent tube.
224. The method according to claim 219, wherein forming the pressure seal comprises  
inflating the piston head.
225. A method comprising:  
25 forming a pressure seal between a wall of a body lumen and a piston head shaped  
so as to define a proximal lobe and a distal lobe in fluid communication with each other;  
and  
advancing the piston head distally through the body lumen by applying fluid  
pressure to an external surface of the piston head.

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226. The method according to claim 225, wherein the lumen includes a gastrointestinal (GI) tract, and wherein forming the pressure seal comprises forming the pressure seal between the wall of the GI tract and the piston head.

227. The method according to claim 226, wherein the GI tract includes a colon, and  
5 wherein forming the pressure seal comprises forming the pressure seal between the wall of the GI tract and the colon.

228. The method according to claim 226, wherein forming the pressure seal comprises placing the piston head in direct contact with the wall of the GI tract.

229. The method according to claim 226, wherein advancing the piston head distally  
10 comprises facilitating passage of fluid out of the GI tract from a site within the GI tract distal to the piston head, via a flexible vent tube that passes through the proximal and distal lobes of the piston head, and opens to the site.

230. A method comprising:  
providing an elongate carrier having a balloon coupled to a distal portion thereof,  
15 the balloon having a hydrophilic substance disposed at an external surface thereof; and  
inserting the elongate carrier through a proximal opening of a body lumen, such that the balloon comes in direct contact with a wall of the lumen.

231. The method according to claim 230, wherein the lumen includes a gastrointestinal (GI) tract, and wherein inserting the elongate carrier comprises inserting the elongate  
20 carrier through the proximal opening of the GI tract.

232. The method according to claim 231, wherein the GI tract includes a colon, and wherein inserting the elongate carrier comprises inserting the elongate carrier through the proximal opening of the colon.

233. A method comprising:  
25 providing an elongate carrier having a balloon coupled to a distal portion thereof, an outer surface of the balloon having a low friction coating suitable for facilitating sliding of the balloon against the wall of the lumen; and  
inserting the elongate carrier through a proximal opening of a body lumen, such that the outer surface of the balloon comes in direct contact with a wall of the lumen.

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234. The method according to claim 233, wherein the lumen includes a gastrointestinal (GI) tract, and wherein inserting the elongate carrier comprises inserting the elongate carrier through the proximal opening of the GI tract.

5 235. The method according to claim 234, wherein the GI tract includes a colon, and wherein inserting the elongate carrier comprises inserting the elongate carrier through the proximal opening of the colon.

236. A method comprising:

providing an elongate carrier having a balloon coupled to a distal portion thereof, the balloon having a characteristic thickness of no more than 20 microns; and

10 inserting the elongate carrier through a proximal opening of a body lumen, such that the balloon comes in direct contact with a wall of the lumen.

237. The method according to claim 236, wherein the lumen includes a gastrointestinal (GI) tract, and wherein inserting the elongate carrier comprises inserting the elongate carrier through the proximal opening of the GI tract.

15 238. The method according to claim 237, wherein the GI tract includes a colon, and wherein inserting the elongate carrier comprises inserting the elongate carrier through the proximal opening of the colon.

239. A method comprising:

forming a pressure seal between a piston head and a wall of a body lumen; and

20 applying fluid pressure to an external surface of the piston head to withdraw the piston head proximally through the body lumen.

240. The method according to claim 239, wherein the lumen includes a gastrointestinal (GI) tract, and wherein forming the pressure seal comprises forming the pressure seal between the piston head and the wall of the GI tract.

25 241. The method according to claim 240, wherein the GI tract includes a colon, and wherein forming the pressure seal comprises forming the pressure seal between the piston head and the wall of the colon.

242. The method according to claim 240, wherein forming the pressure seal comprises placing the piston head in direct contact with the wall of the GI tract.

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243. The method according to claim 240, comprising facilitating passage of fluid out of the GI tract from a proximal site within the GI tract proximal to the piston head.

244. The method according to claim 240, wherein forming the pressure seal comprises inflating the piston head.

5 245. A method comprising:

inserting an annular balloon at least partially into a proximal opening of a body lumen;

expanding the balloon to form a seal between the balloon and a wall of the body lumen in a vicinity of the proximal opening;

10 inserting an elongate carrier into the lumen through an opening that passes through the balloon; and

applying pressure to an interior of the lumen distal to the balloon.

246. The method according to claim 245,

wherein the body lumen includes a colon,

15 wherein the proximal opening includes a rectum,

wherein inserting the balloon comprises inserting the balloon at least partially into the rectum, and

wherein expanding the balloon comprises expanding the balloon to form the pressure seal between the balloon and the wall of the colon.

20 247. The method according to claim 246, wherein expanding the balloon comprises applying pressure to an interior of the balloon using a syringe. .

248. A method comprising:

inserting an inflatable cuff at least partially into a proximal opening of a body lumen;

25 inflating the cuff to form a seal with a wall of the body lumen in a vicinity of the proximal opening; and

inserting an elongate carrier into the lumen through an opening that passes through the cuff.

249. The method according to claim 248, wherein the body lumen includes a colon,  
30 wherein the proximal opening includes a rectum, and wherein inflating the cuff comprises inflating the cuff to form the seal with the wall of the colon in the vicinity of the rectum.

250. A method comprising:

inserting, through a proximal opening of a body lumen, an elongate carrier having an image-capturing device fixed thereto in a vicinity of a distal end thereof; and

5 spraying, from one or more openings in the distal end of the carrier, fluid onto at least a portion of the image-capturing device.

251. The method according to claim 250, wherein the body lumen includes a colon, and wherein inserting the carrier comprises inserting the carrier through the proximal opening of the colon.

252. A method comprising:

10 inserting, through a proximal opening of a body lumen, an elongate carrier having an image-capturing device fixed thereto in a first vicinity of a distal end of the carrier, for providing omnidirectional lateral viewing; and

15 increasing a diameter of the carrier in a second vicinity of the distal end to an extent sufficient to position the image-capturing device a distance from a wall of the lumen sufficient to enable omnidirectional focusing of the image-capturing device.

253. The method according to claim 252, wherein the lumen includes a gastrointestinal (GI) tract, and wherein inserting the carrier comprises inserting the carrier through the proximal opening of the GI tract.

20 254. The method according to claim 253, wherein increasing the diameter comprises increasing the diameter of the carrier in the second vicinity such that the image-capturing device is at least 15 mm from the wall.

255. The method according to claim 253, wherein the GI tract includes a colon, and wherein inserting the carrier comprises inserting the carrier through the proximal opening of the colon.

25 256. The method according to claim 255, wherein increasing the diameter comprises increasing the diameter of the carrier in the second vicinity to between 30 and 45 mm.

257. A method comprising:

forming a pressure seal between an inflatable piston head and a wall of a body lumen;



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measuring a first measurable pressure in a proximal portion of the lumen proximal to the piston head, and a second measurable pressure in the piston head; and advancing the piston head distally through the lumen by:

5       applying a first applied pressure to the proximal portion of the lumen, and

          regulating the second measurable pressure in the piston head to be equal to the first measurable pressure in the proximal portion of the lumen plus a positive value, by applying a second applied pressure to piston head.

10   258.   The method according to claim 257, wherein the lumen includes a gastrointestinal (GI) tract, and wherein forming the pressure seal comprises forming the pressure seal between the piston head and the wall of the GI tract.

          259.   The method according to claim 258, wherein the GI tract includes a colon, and wherein forming the pressure seal comprises forming the pressure seal between the piston  
15   head and the wall of the colon.

260.   The method according to claim 258, wherein forming the pressure seal comprises placing the piston head in direct contact with the wall of the GI tract.

261.   The method according to claim 258, comprising facilitating passage of fluid out of the GI tract from a portion of the GI tract distal to the piston head.

20   262.   The method according to claim 258, wherein the positive value is between 1 and 5 millibar.

263.   The method according to claim 262, wherein the positive value is between 1.5 and 2.5 millibar.

264.   The method according to claim 258, wherein regulating the second measurable  
25   pressure comprises setting the second measurable pressure in the piston head at an initial value prior to application of the first applied pressure.

265.   The method according to claim 264, wherein the initial value is between 5 and 15 millibar, and wherein setting the second measurable pressure comprises setting the second measurable pressure at between 5 and 15 millibar.

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266. The method according to claim 264, wherein regulating the second measurable pressure comprises regulating the second measurable pressure to be equal to the greater of: (a) the initial value, and (b) the first measurable pressure plus the positive value.

267. A method comprising:

5       forming a pressure seal between a distal piston head and a wall of a body lumen;  
and

          applying fluid pressure to an external surface of the distal piston head to advance the piston head distally through the lumen.

268. The method according to claim 267, wherein the lumen includes a gastrointestinal  
10 (GI) tract, and wherein forming the pressure seal comprises forming the pressure seal between the distal piston head and the wall of the GI tract.

269. The method according to claim 268, wherein the GI tract includes a colon, and wherein forming the pressure seal comprises forming the pressure seal between the distal piston head and the wall of the colon.

15 270. The method according to claim 268, wherein forming the pressure seal comprises placing the distal piston head in direct contact with the wall of the GI tract.

271. The method according to claim 268, comprising facilitating distal advancement of the distal piston head by facilitating passage of fluid out of the GI tract from a distal site within the GI tract distal to the distal piston head.

20 272. The method according to claim 271, wherein facilitating the passage of the fluid comprises facilitating the passage of an amount of the fluid out of the GI tract from the distal site sufficient to maintain a pressure of less than 10 millibar at the distal site.

273. The method according to claim 271, wherein facilitating the passage of the fluid comprises facilitating the passage of at least 100 cc of the fluid out of the GI tract from  
25 the distal site, per minute that the distal piston head advances distally.

274. The method according to claim 273, wherein facilitating the passage of the fluid comprises facilitating the passage of at least 300 cc of the fluid out of the GI tract from the distal site, per minute that the distal piston head advances distally.

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275. The method according to claim 271, wherein facilitating the passage of the fluid comprises facilitating the passage of at least 3 cc of the fluid out of the GI tract from the distal site, per centimeter that the distal piston head advances distally.

276. The method according to claim 275, wherein facilitating the passage of the fluid  
5 comprises facilitating the passage of at least 10 cc of the fluid out of the GI tract from the distal site, per centimeter that the distal piston head advances distally.

277. The method according to claim 271, wherein facilitating the passage of the fluid comprises facilitating the passage of the fluid out of the GI tract from the distal site within the GI tract through a vent tube.

10 278. The method according to claim 277, wherein facilitating the passage of the fluid comprises passively permitting the passage of the fluid out of the GI tract from the distal site within the GI tract.

279. The method according to claim 277, wherein facilitating the passage of the fluid comprises actively facilitating the passage of the fluid out of the GI tract from the distal  
15 site within the GI tract, by applying suction to a proximal end of the vent tube.

280. The method according to claim 279, wherein actively facilitating the passage of the fluid comprises regulating a pressure distal to the distal piston head to be between -5 millibar and +15 millibar.

281. The method according to claim 271, wherein forming the pressure seal comprises  
20 inflating the distal piston head, and wherein facilitating the passage of the fluid comprises intermittently deflating, at least in part, the distal piston head, while in the GI tract.

282. The method according to claim 268, wherein forming the pressure seal comprises inflating the distal piston head.

283. The method according to claim 282, comprising forming, at a position proximal to  
25 the distal piston head, an auxiliary pressure seal between an auxiliary piston head and the wall of the GI tract, by inflating the auxiliary piston head.

284. The method according to claim 282, wherein inflating the distal piston head comprises sensing a pressure within the distal piston head.

285. The method according to claim 282, comprising sensing a pressure within the GI  
30 tract distal to the distal piston head.

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286. The method according to claim 282, wherein inflating the distal piston head comprises inflating the distal piston head to an inflation pressure between 10 and 60 millibar during advancement through the GI tract.

287. The method according to claim 282, comprising sensing a first measurable pressure, within a proximal portion of the GI tract proximal to the distal piston head.

288. The method according to claim 287, comprising sensing a pressure distal to the distal piston head.

289. The method according to claim 287, wherein inflating the distal piston head comprises sensing a second measurable pressure within the distal piston head.

290. The method according to claim 289, wherein applying the fluid pressure comprises applying a first applied pressure to the proximal portion of the GI tract,

wherein inflating the distal piston head comprises applying a second applied pressure to an interior of the distal piston head, and

wherein applying the fluid pressure comprises advancing the distal piston head distally in the GI tract by:

while applying the first applied pressure to the proximal portion,

regulating the second measurable pressure in the distal piston head to be equal to the first measurable pressure in the proximal portion of the GI tract plus a positive value, by applying the second applied pressure.

291. A method comprising:

forming a pressure seal between a piston head and a wall of a body lumen;

applying fluid pressure to an external surface of the distal piston head to advance the piston head distally through the lumen; and

sensing, at a vicinity of a proximal opening of the lumen, a piston head pressure in the piston head.

292. The method according to claim 291, wherein the lumen includes a gastrointestinal (GI) tract, and wherein forming the pressure seal comprises forming the pressure seal between the piston head and the wall of the GI tract.

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293. The method according to claim 292, wherein the GI tract includes a colon, and wherein forming the pressure seal comprises forming the pressure seal between the piston head and the wall of the colon.

294. The method according to claim 292, wherein forming the pressure seal comprises  
5 placing the piston head in direct contact with the wall of the GI tract.

295. The method according to claim 292, wherein sensing the piston head pressure comprises sensing the piston head pressure via a passageway in fluid communication with an interior of the piston head, when a proximal end of the passageway is disposed in the vicinity of the proximal opening of the GI tract.

10 296. The method according to claim 292, wherein sensing the piston head pressure comprises sensing the piston head pressure from outside of the GI tract.

297. The method according to claim 292, wherein sensing the piston head pressure comprises sensing the piston head pressure via a passageway, and comprising applying fluid pressure to an interior of the piston head via the passageway.

15 298. The method according to claim 292, comprising sensing, at a vicinity of the proximal opening of the GI tract, a proximal portion pressure in the proximal portion of the GI tract.

299. The method according to claim 298, wherein sensing the proximal portion pressure comprises sensing the proximal portion pressure from outside of the GI tract.

20 300. The method according to claim 292, comprising sensing, at a vicinity of the proximal opening of the GI tract, a distal portion pressure in a distal portion of the GI tract distal to the piston head.

301. The method according to claim 300, wherein sensing the distal portion pressure comprises sensing the distal portion pressure from outside of the GI tract.

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**ABSTRACT**

Apparatus is provided for use with a biologically-compatible-fluid pressure source, the apparatus including an elongate carrier, adapted to be inserted through a proximal opening of a body lumen, and a piston head coupled to a distal portion of the carrier. The piston head is adapted to form a pressure seal with a wall of the lumen after the carrier has been inserted into the lumen, and to be advanced distally through the body lumen in response to pressure from the fluid pressure source. The apparatus is configured to facilitate distal advancement of the piston head by facilitating passage of fluid out of the lumen from a site within the lumen distal to the piston head. The apparatus additionally includes an optical system, coupled to the carrier in a vicinity of the distal portion, the optical system having distal and proximal ends. The optical system includes an image sensor, positioned at the proximal end of the optical system; an optical member having distal and proximal ends, and shaped so as to define a lateral surface, at least a distal portion of which is curved, configured to provide omnidirectional lateral viewing; and a convex mirror, coupled to the distal end of the optical member, wherein the optical member and the mirror have respective rotational shapes about a common rotation axis.

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: **OZ CABIRI, et al**  
Serial No.: \_\_\_\_\_ Group No.: \_\_\_\_\_  
Filed: \_\_\_\_\_ Examiner: \_\_\_\_\_  
For: **PRESSURE-PROPELLED SYSTEM FOR BODY LUMEN**

Attorney Docket No.: **U 015413-4**

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**WRITTEN ASSERTION OF SMALL ENTITY STATUS**

This is written assertion on the basis of:

- ☐ personal knowledge;  
☐ applicant's letter of \_\_\_\_\_;  
☒ applicant's agent's letter of OCTOBER 17, 2004; or  
☐ other \_\_\_\_\_

by a practitioner (not necessarily of record) that the above application is entitled to small entity status and, therefore, fees.

---

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- (i) Be clearly identifiable;
- (ii) Be signed (see paragraph (c)(2) of this section); and
- (iii) Convey the concept of entitlement to small entity status, such as by stating that applicant is a small entity, or that small entity status is entitled to be asserted for the application or patent. While no specific words or wording are required to assert small entity status, the intent to assert small entity status must be clearly indicated in order to comply with the assertion requirement."

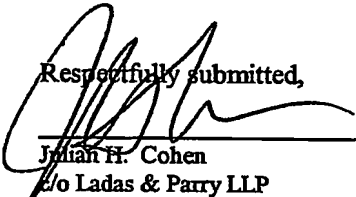
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- (ii) At least one of the individuals identified as an inventor (even though a § 1.63 executed oath or declaration has not been submitted), notwithstanding § 1.33(b)(4), who can also file the written assertion pursuant to the exception under § 1.33(b) of this part; or
- (iii) An assignee of an undivided part interest, notwithstanding §§ 1.33(b)(3) and 3.73(b) of this chapter, but the partial assignee cannot file the assertion without resort to a party identified under § 1.33(b) of this part."

35 C.F.R. § 1.33(b):

- (b) Amendment and other papers. Amendments and other papers, except for written assertions pursuant to § 1.27(c)(2)(ii) of this part, filed in the application must be signed by:
  - (1) A registered attorney or agent of record appointed in compliance with § 1.34(b);
  - (2) A registered attorney or agent not of record who acts in a representative capacity under the provisions of § 1.34(a);
  - (3) An assignee as provided for under § 3.71(b) of this chapter; or
  - (4) All of the applicants (§ 1.41(b)) for patent, unless there is an assignee of the entire interest and such assignee has taken action in the application in accordance with § 3.71 of this chapter.

Respectfully submitted,

  
Julian H. Cohen  
C/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, N. Y. 10023



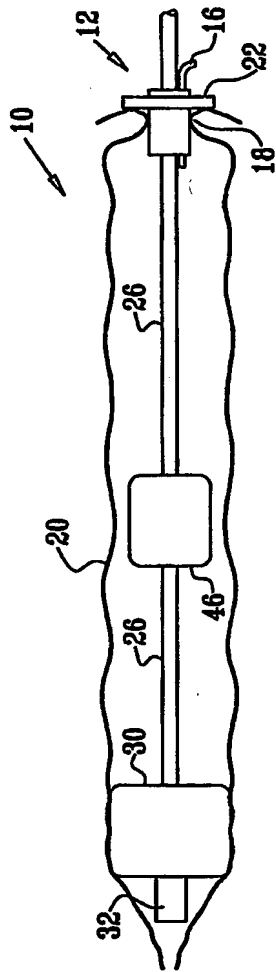


FIG. 1

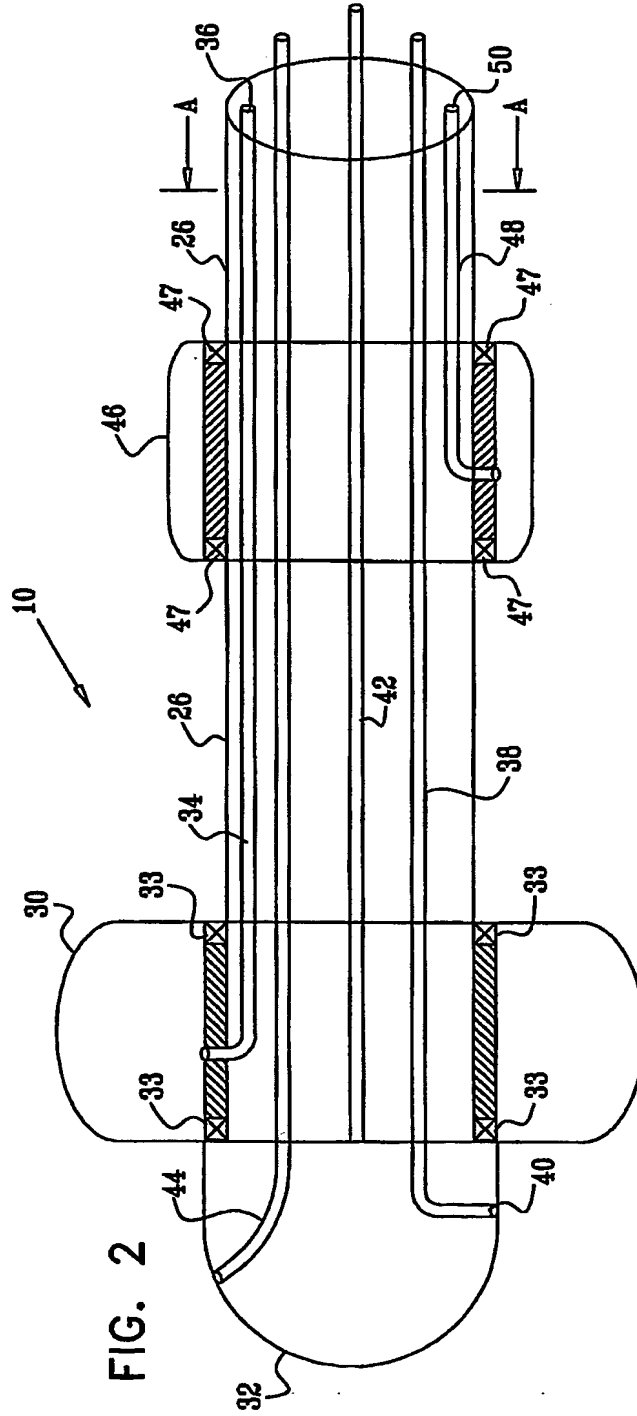


FIG. 2

FIG. 3

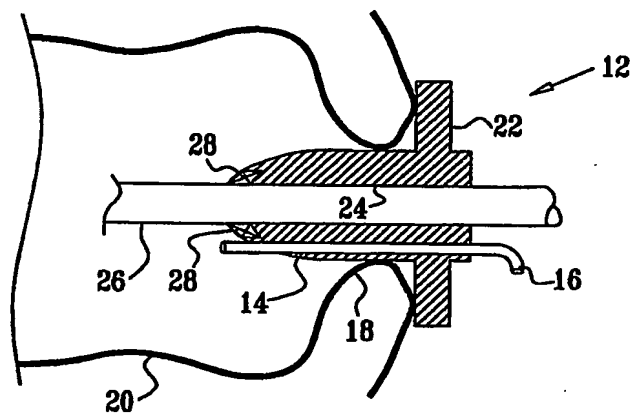
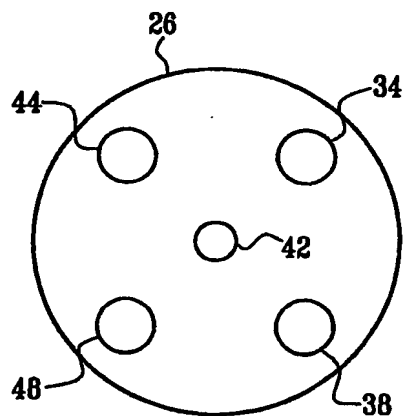
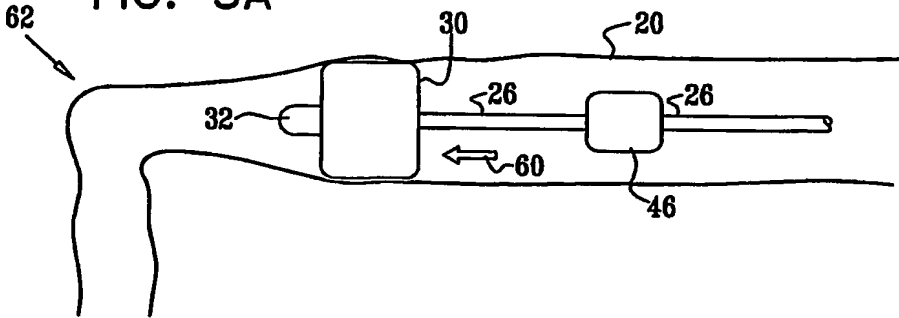


FIG. 4



**FIG. 5A**



**FIG. 5B**

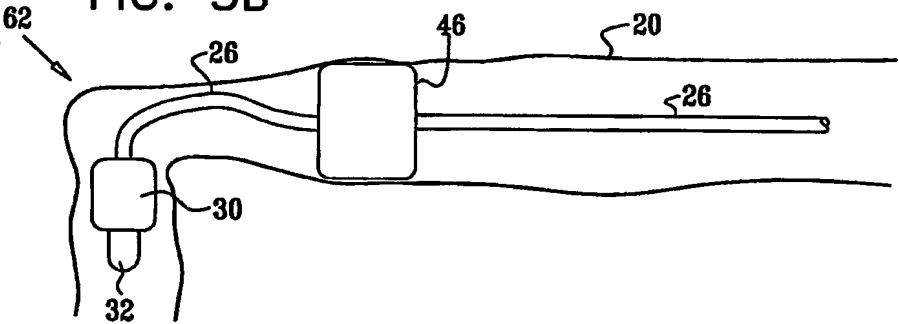


FIG. 5C

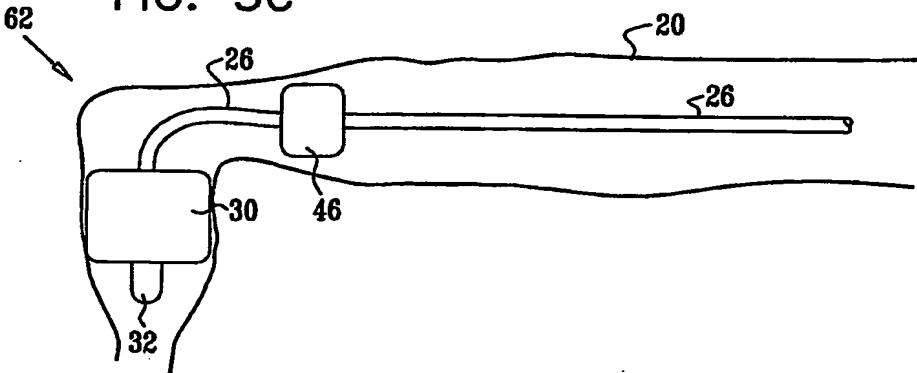
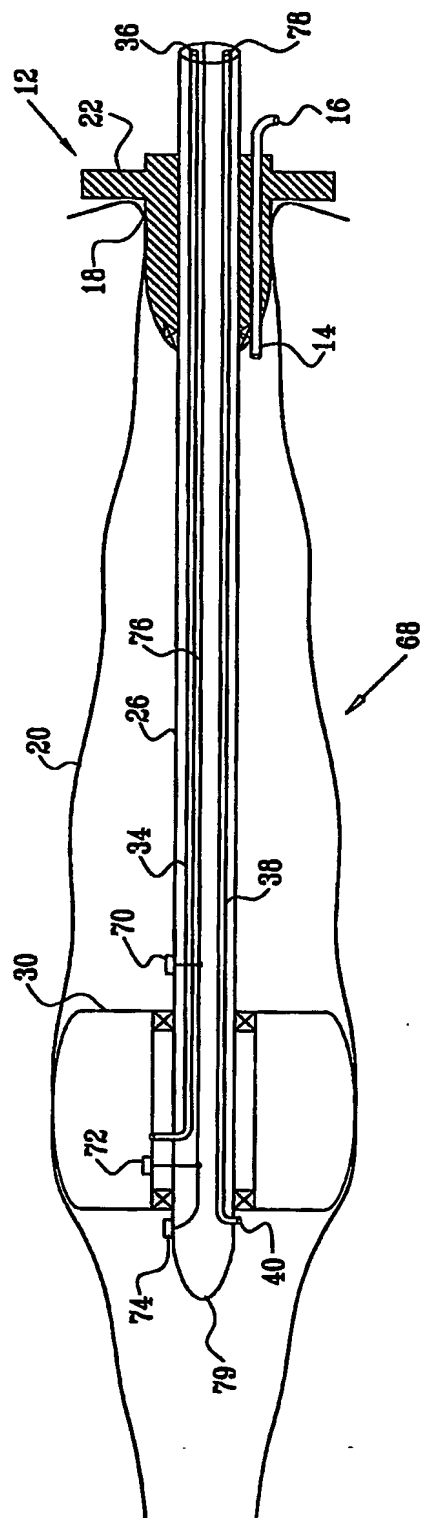


FIG. 6



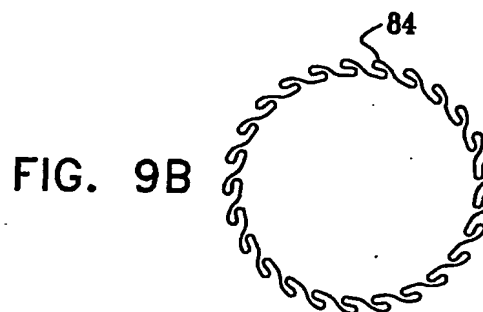
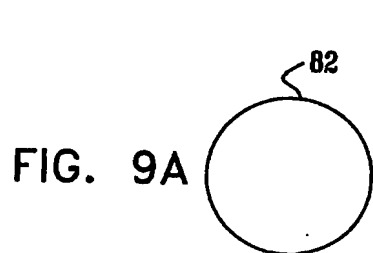
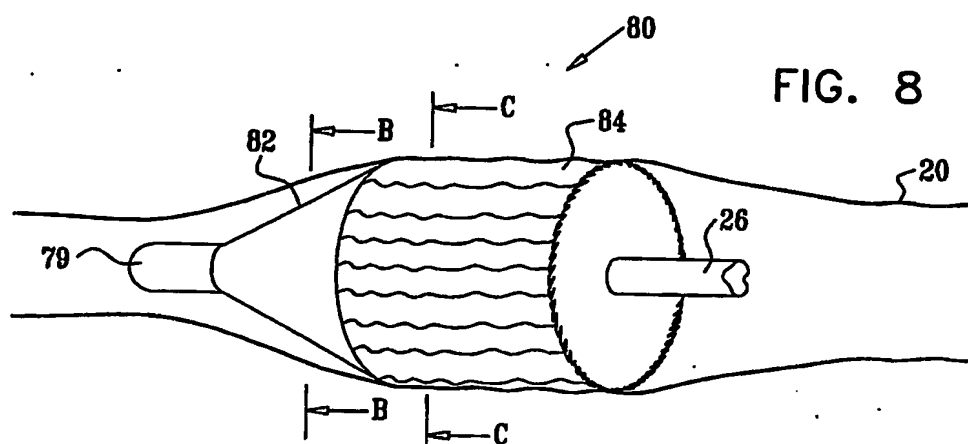
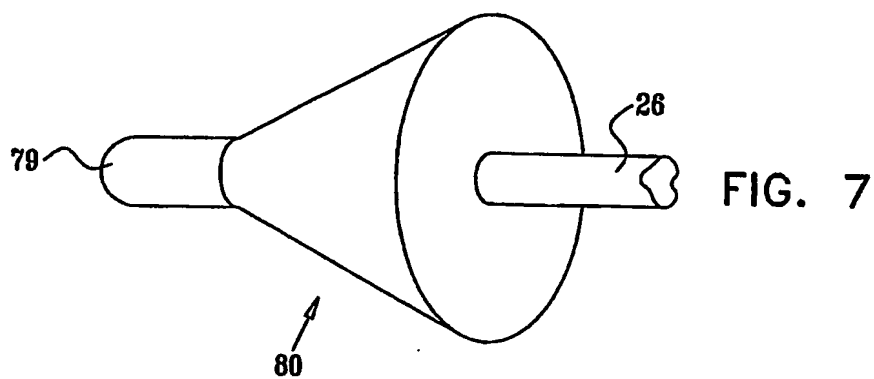


FIG. 10A

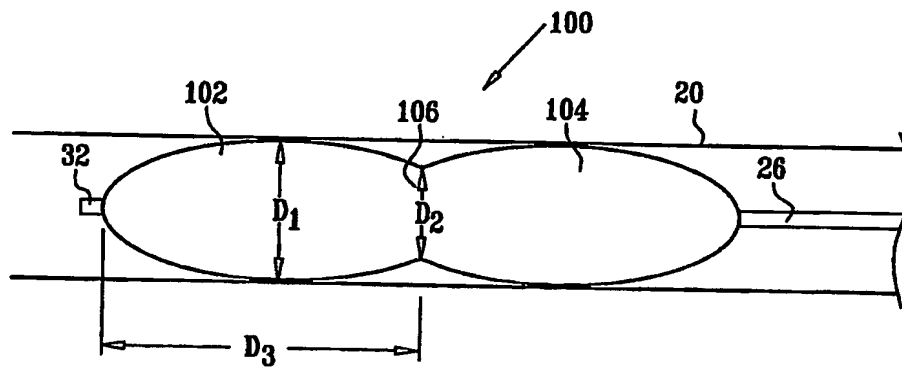


FIG. 10B

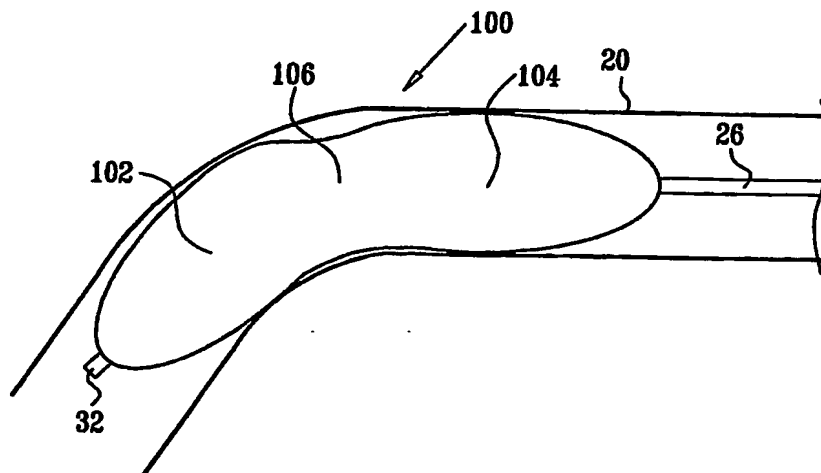


FIG. 11A

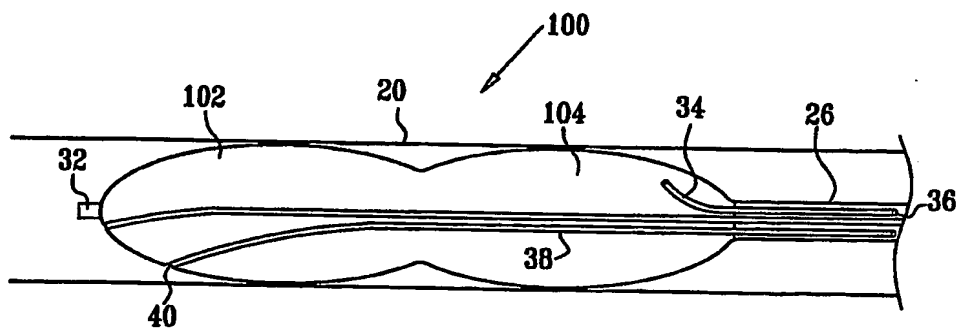


FIG. 11B

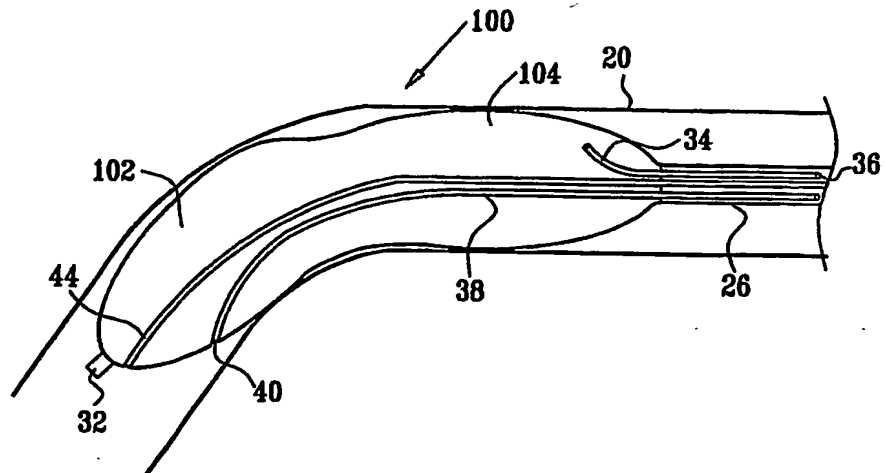


FIG. 12

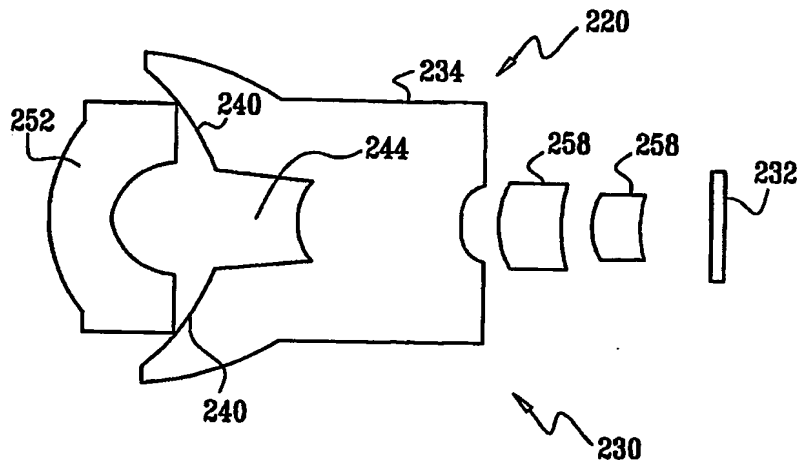


FIG. 13A

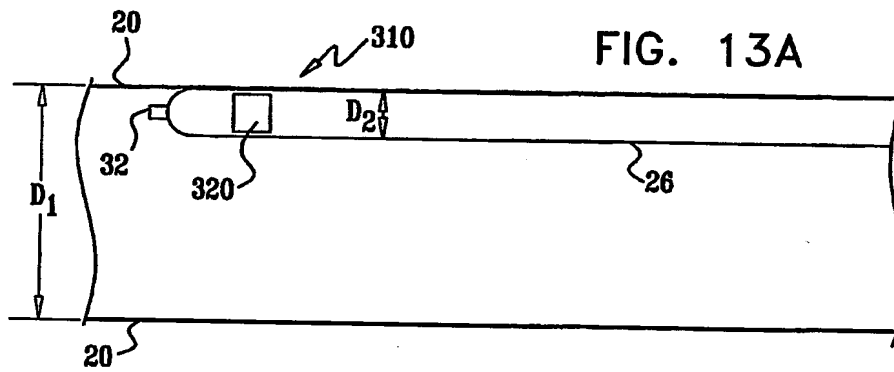


FIG. 13B

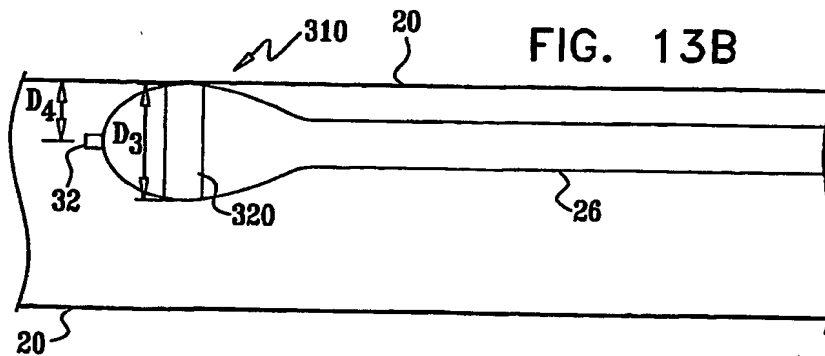




FIG. 14

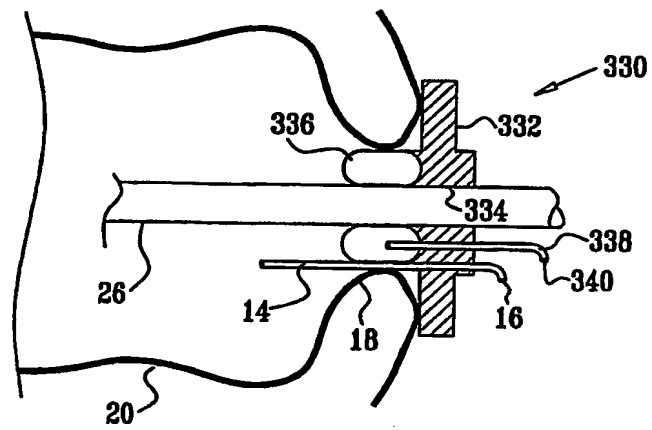
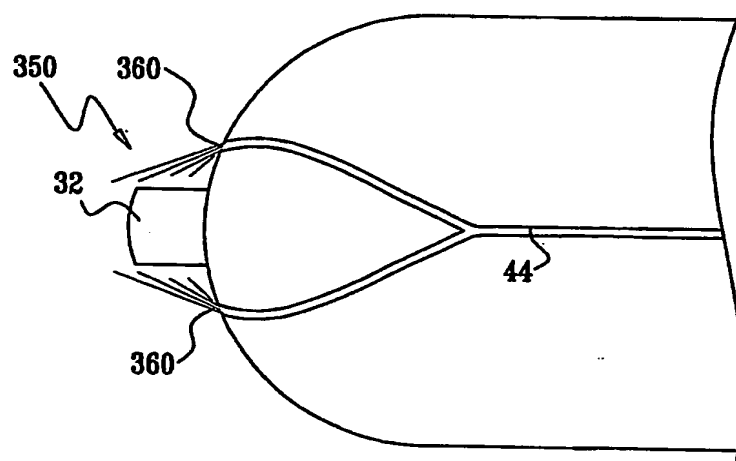


FIG. 15



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